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Guidance for the Reregistration of Pesticide Products Containing Nabam as the Active Ingredient

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April 1987

Pesticides

EPA

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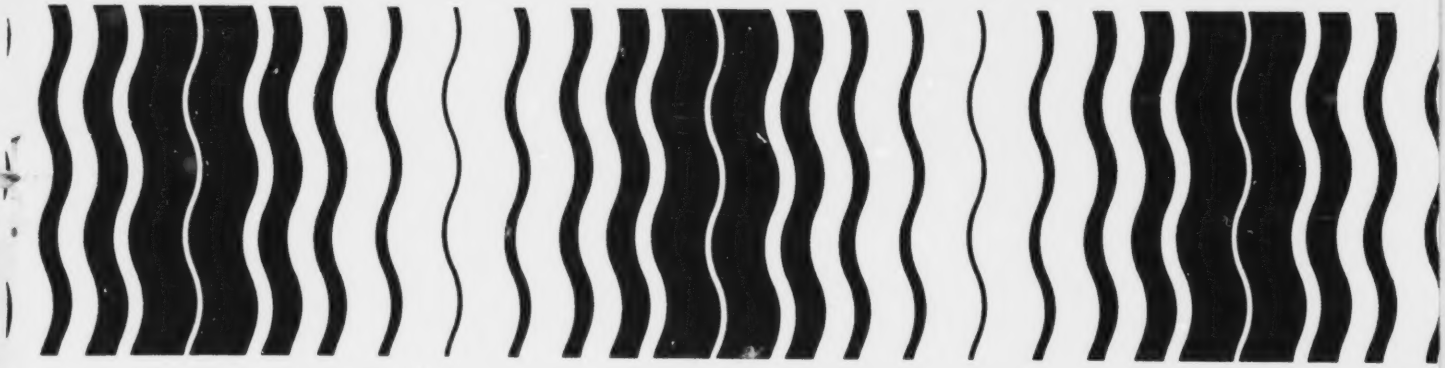

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
NABAM
AS THE ACTIVE INGREDIENT

GS-0641

CHEMICAL ABSTRACTS SERVICE (CAS) NUMBER: 142-59-6

EPA SHAUGHNESSY CODE: 014503

APRIL 1987

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C.

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EPA Form 8570-27	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

The following terms are used throughout this Registration Standard and are defined here for the convenience of the reader.

ADI: (Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a complete data base.

A/D Ratio: This ratio determines a level of concern regarding whether effects observed in embryos and fetuses from treated females are "primary" (due to direct compound-related effects) or "secondary" (to maternal toxicity). Thus, the NOEL for maternal effects ("A" numerator) divided by the embryo/fetal NOEL ("D" for "developmental"), including frank terata (gross congenital defects), defines this concern. If A/D is less than "1", developmental toxicity of a substance may be ascribed to secondary effects of maternal toxicity; if greater than 2, the substance is considered a direct (primary) developmental toxicant. Scientific interpretation is required in the range, 1 to 2 (LEL's may be used; or effects from other types of studies, e.g., reproduction).

ai: Active ingredient

CAS: Chemical Abstract Society (number)

Core Classification: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline)

Core Guideline: Studies which satisfy Agency data requirements.

Core Minimum: Studies which are acceptable to support registration of pesticide products but were not necessarily done according to Agency guidelines.

Core Supplementary: Studies in this category are scientifically sound, thus the information may be useful. However, the studies were performed under conditions that deviated substantially from recommended protocols. Studies do not meet guideline requirements and thus do not support registration of a product.

EEC: (Estimated Environmental Concentration) Estimated pesticide concentration in the environment (terrestrial or aquatic ecosystem).

EP: End-use Product

EPA: The Environmental Protection Agency, also "the Agency"

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

HDT: Highest dose tested

Invalid: Studies which are deficient in some *vital* parameter or those studies which have been judged *not* to be scientifically sound or those studies whose reliability is seriously questioned.

LC_{50}: (median lethal concentration): a statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/L or ppm).

LD_{50}: (median lethal dose): a statistically derived single dose that can be expected to cause death in 50 percent of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

MOS: Margin of Safety - The calculation of a margin of safety involves division of an appropriate NOEL by a worker's estimated exposure. The result is a unitless figure which gives an indication of how close a worker's internal dose is in relation to the NOEL for laboratory animals.

MPI: Maximum Permissible Intake

MRID: Master Record Identification (number)--EPA's system of tracking studies used in support of registrations.

MP: Manufacturing-use product

NPDES: National Pollution Discharge Elimination System

NOEL: No Observed Effect Level--the maximum dose used in a test which produces no observed adverse effects.

OPP: The Office of Pesticide Programs (EPA)

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

OM: Organic matter (used to describe soils)

ppm: Parts per million

PADI: (Provisional Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a limited data base.

PAI: Pure active ingredient

Technical: Active ingredient as manufactured

TMRC: (Theoretical Maximum Residue Contribution) An estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figures for each crop. TMRC is usually expressed in terms of mg ai/day, assuming a 60 kg person.

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

Common Name: Nabam

Chemical Name: Disodium ethylene bisdithiocarbamate

Chemical Abstracts
Service (CAS) Number: 142-59-6

EPA Shaughnessy Number: 014503

Empirical Formula: $C_4H_6N_2Na_2S_4$

Trade Names: Chem Bam; Dithane D-14; Dithane A-40; DSE; Nabasan; Parzate; Spring-Bak.

B. USE PROFILE

Type of Pesticide: Broad spectrum fungicide.

Pests Controlled: Bacteria, fungi, algae, protozoa

Registered Uses: Industrial sites (cooling towers, evaporative condensers, air washer systems, secondary oil recovery water and drilling fluids, pulp and paper mills, cane sugar mills, beet sugar mills). All registered food (except for use in sugar mill flume water) and ornamental uses of nabam, a total of 35, are currently suspended. Technical nabam products may not be formulated into end-use products for field or food crop uses.

Predominant Uses: Water cooling towers.

Mode of Activity: Enzyme activity inhibition.

Formulation Types Registered: Formulation Intermediates - 22.5, 25, and 30% nabam.
Ready-to-Use - 3.75 to 22% nabam.
Soluble Concentrate - 22% or 93% nabam.

Methods of Application: In industrial uses, nabam is added directly to water either by a single dose or continuous feed.

Major Uses: Domestic usage of nabam as a pesticide (Typical current year basis (1983-1985)):

Sector	lbs. x 1,000	Percent
Cooling Water	475	40
Sugar	425	37
Paper	275	23
Totals	1175	100

C. BACKGROUND

Nabam is one of six chemicals classified as ethylene bisdithiocarbamate (EBDC) fungicides. These broad spectrum fungicides are used to prevent crop damage by fungi, to protect harvested products from deterioration, or as industrial biocides. The chemical structure of nabam and the other EBDC's (amobam, maneb, metiram, mancozeb, and zineb) and their metabolite, ethylenethiourea (ETU) are depicted in Figure 1.

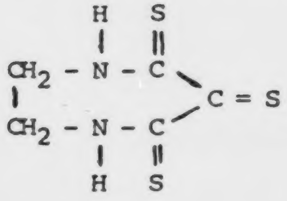
The chemistry of the EBDC's is complicated by their instability and their propensity to form polymers. While the solubilities of several of the EBDC's in water and other solvents vary from insoluble to completely soluble, nabam is completely soluble in water. The EBDC's are generally unstable in the presence of moisture and oxygen, as well as in biological systems. A common contaminant, degradation product, and metabolite of all EBDC's is ETU, an odorless white crystalline solid that is soluble in water but insoluble in common organic solvents. EBDC residues, in or on foods, are known to convert readily to ETU during commercial processing or home cooking.

In 1977, the Agency initiated a Special Review (formerly referred to as Rebuttable Presumption Against Registration [RPAR]) of the EBDC's. The Special Review process is designed to help the Agency determine whether to initiate procedures to cancel, deny or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of FIFRA. This process is set forth in 40 CFR 154, which describes various risk criteria and provides that a Special Review may arise if the Agency determines that any of these criteria have been met.

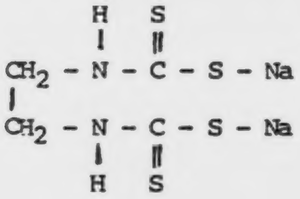
The EBDC Special Review was based on the presumption that the EBDC's and the metabolite, ETU, posed three kinds of risk to human health or the environment: oncogenicity, teratogenicity, and acute toxicity to aquatic organisms. Three additional areas of concern were also identified: thyroid toxicity, mutagenicity, and skin sensitization. Skin sensitization was subsequently determined not to meet a special review criterion.

Figure 1

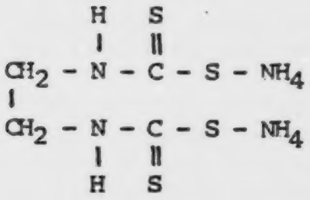
ETHYLENE THIOUREA (ETU)



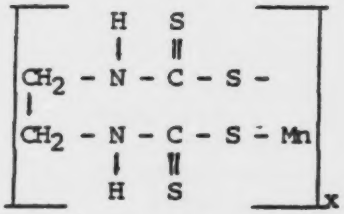
NABAM



AMOBAM



MANEB



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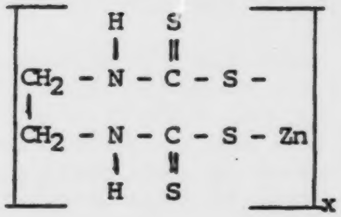
ZINEB



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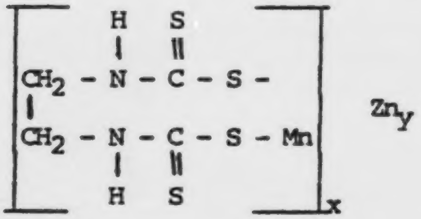
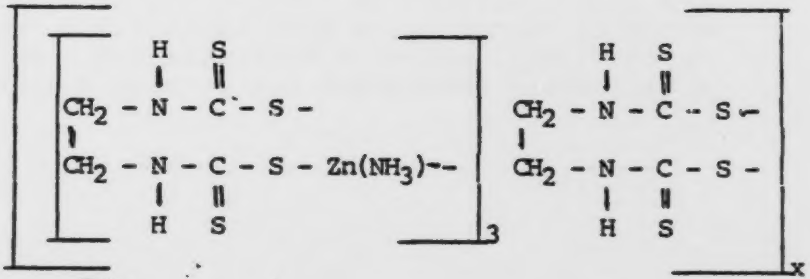
MANCOZEB



METIRAM



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The Agency evaluated these potential risks in depth, taking into account uncertainties associated with the risk estimates, considering the significant benefits of the EBDC's and weighing various regulatory options. In 1982, the Agency issued its Decision Document on all EBDC's reporting on the results of the evaluation. This evaluation resulted in the following conclusions.

1. The potential risk of acute toxicity to aquatic organisms resulting from use of mancozeb on commercially grown wild rice would be mitigated through present cultivating practices and the addition of a statement to the label warning users of a hazard to fish.

2. Potential risks of teratogenicity and thyroid toxicity to commercial and agricultural applicators would be adequately reduced by requiring protective clothing.

3. Potential dietary exposure resulting from consumption of home grown produce could be reduced by highlighting preharvest intervals on labels of noncommercial (home use) products used by home gardeners.

4. The issues of whether EBDC's or ETU pose a potential risk of oncogenicity, mutagenicity, teratogenicity, and thyroid effects to man were subject to many uncertainties. Available data on oncogenicity and mutagenicity were not adequate to resolve key scientific issues such as the mechanism of action of EBDC's and ETU. Additional data on the EBDC's and ETU were needed for the Agency to determine their mutagenic potential and to assess human exposure and oncogenic risk. Some data would be required at termination of the Special Review while further data needs, with particular emphasis on chronic studies, dietary residues and exposure, would be identified during a later reregistration review. Data needs identified at that time included:

    a. Metabolism studies designed to define the in vivo conversion of the various EBDC's to ETU and other metabolites.

    b. Dermal absorption studies designed to demonstrate the dermal penetration of each of the EBDC's and ETU.

    c. Five mutagenicity studies on each of the six registered EBDC's.

    d. Mammalian cell transformation assays on each of the six EBDC's and ETU.

With the issuance of the Decision Document, the Agency concluded the special review and returned the EBDC's to the registration process on the condition that registrants comply with the label changes and data requirements specified in the Decision Document.

Since issuance of the Decision Document, the Agency has issued five data call-in notices for nabam as follows:

1. January 17, 1983: This notice required the submission of the metabolism, dermal penetration and mutagenicity data identified in the 1982 Decision Document.

2. July 25, 1984: This notice advised registrants of the Agency's concern about the existence of pesticides in ground water and the designation of a number of chemicals, including nabam, which may have the potential to contaminate ground water. The chemicals were designated based on such factors as chemical structure, solubility, and use patterns. The notice required submission of certain environmental fate and product chemistry data for the agricultural uses only.

3. October 19, 1984: This notice required dietary exposure, product chemistry and toxicological (subchronic feeding and inhalation) data considered necessary to reassess the registration status of nabam.

4. March 20, 1985: This notice required registrants of pesticide products containing nabam to submit all outstanding data requirements as outlined under 40 CFR 158 regulations for disciplines including product chemistry, toxicology, wildlife and aquatic organisms, and envirnomental fate.

5. April 30, 1985: This notice required additional data, not identified in the October 1984 call-in notice, but considered necessary to the reassessment of the chemicals. These data were additional toxicological (subchronic feeding and inhalation - ETU) and residue data for ETU as well as nabam.

The data required by these call-in notices to support the continued registration of nabam products have been received and considered by the Agency in its evaluation of nabam, as presented in the assessment section of this Standard. Nabam technical product registrations were amended in 1985 to include a restriction which prohibited the use of such products for formulation into pesticide products to be used on field or food crops. Moreover, all registered end-use nabam products with agricultural field or food crop uses have been suspended because the registrants of the products did not commit to submit (and failed to provide evidence that they were taking steps to submit) the data required to support continued registration of the agricultural field or food crops uses of nabam, following the decision by the basic nabam producer not to support those uses. Due to the prohibition on the use of technical products, as noted above, and the suspension of the end-use products with agricultural field or food crop uses, there are no remaining agricultural food or field crop uses of nabam pesticide products. Some suspended end-use nabam pesticide products are also labeled for terrestrial non-food uses; no other nabam pesticide products are labeled for terrestrial non-food uses. Therefore, as in the case of agricultural field or food crop use, all terrestrial non-food use of nabam pesticide products are currently suspended.

III. AGENCY ASSESSMENT

A. SUMMARY

Based on the review of available data, the Agency has reached the conclusions set forth in this Standard. A summary of those conclusions follow. A more detailed discussion is contained in the remainder of this Chapter.

1. A major toxicological concern from exposure to nabam is the hazard to the human thyroid from presence of ethylenethiourea (ETU), a contaminant, degradation product, and metabolite present in nabam and other EBDC products. Additional chronic studies on nabam are required for further evaluation.

2. ETU has caused developmentally toxic/teratogenic effects in rats and hamsters. There are no adequate teratology studies on nabam. Teratology studies with nabam are required before its teratogenicity can be fully assessed.

3. ETU has been classified as a Group B2 carcinogen in accordance with the Agency's Guidelines for Carcinogen Risk Assessment (September 26, 1986, 51 CFR 33992), based on studies which show that it induced an increased incidence of thyroid adenomas and adenocarcinomas in rats and hepatomas in mice.

4. Because of the presence of ETU in nabam, the Agency is considering whether further regulatory actions are warranted.

As a result of this review, the Agency has identified missing data needed to further evaluate the environmental and human risks associated with the use of nabam. These data must be submitted in order to maintain registrations of products or register new products containing nabam. A summary of these data gaps appears in Table 1. Note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Agency has also determined that certain label restrictions or revisions are necessary in order for nabam products to remain in compliance with FIFRA, as indicated below. Chapter IV, Section D, Labeling, contains the specific wording for each of the labeling statements and identifies the products to which each labeling statement applies.

- Protective clothing requirements
- Environmental hazard precautions
- Reentry interval
- Worker safety rules
- Preharvest interval emphasis

The Regulatory Position and Rationale section discusses the Agency's position regarding nabam.

Table 1.

Summary of Data Gaps for Nabam*

Nabam

Product Chemistry - All

Residue Chemistry - Plant and animal metabolism
Residue studies

Toxicology - Acute dermal and inhalation toxicity
Primary eye and dermal irritation
21-Day subchronic dermal toxicity
Chronic toxicity (rodent and nonrodent) (food uses)
Oncogenicity (rat and mouse)(food uses)
Teratology (rabbit and rat)
Reproduction (rat)(food uses)
Mutagenicity (gene mutation, cell transformation, unscheduled DNA sysnthesis)

Ecological Effects - Avian oral toxicity
Avian dietary toxicity
Freshwater fish toxicity
Freshwater invertebrate toxicity
Estuarine and marine organism toxicity
Aquatic organism accumulation
Simulated or actual field testing-aquatic organisms
Nontarget area phytotoxicity-aquatic plant growth

Environmental Fate - Hydrolysis
Photodegradation (water, soil)
Aerobic and anaerobic soil metabolism
Aerobic and anaerobic aquatic metabolism
Leaching and adsorption/desorption
Volatility (laboratory)
Field dissipation (terrestrial,aquatic)
Rotational crops (confined)
Fish accumulation
Reentry protection studies

Ethylenethiourea (ETU)

Toxicology - Chronic (rodent and non-rodent)
Reproduction
Dermal (percutaneous) absorption
Mutagenicity (promotion)

Environmental Fate - Hydrolysis
Photodegradation (soil and water)
Aerobic and anaerobic soil metabolism
Leaching and adsorption/desorption
Degradation (soil)

*Refer to Appendix A, Data Tables, for detailed information

B. PRELIMINARY RISK ASSESSMENT

Toxicological Studies - Nabam. In its review of nabam, the Agency has considered the available data as summarized below:

1. Acute Toxicity and Irritation Studies. Adequate data are available to define the acute oral toxicity of technical nabam products (LD_{50}=395 mg/kg/bw) as moderately toxic (Toxicity Category II). There are no valid data to characterize the acute dermal and inhalation toxicity or eye and skin irritation of technical nabam. These studies are required to support the continued registration of nabam products.

   Skin sensitization was identified as an area of concern during the special review of the EBDC's. At that time, the Agency reviewed skin sensitization data submitted on other EBDC's and concluded that the EBDC's are potential, however not potent, skin sensitizers. A study in the open literature reported that a sensitization reaction in humans was noticed following exposure to a 19% nabam solution. This study adequately demonstrates that nabam is a skin sensitizer and no further dermal sensitization data are required at this time.

2. Subchronic Testing

   Oral (Rodent, Nonrodent) Studies. There is no valid subchronic 90-day feeding study for either rodents or nonrodents available on nabam. These studies are not required to support the continued registrations of nabam for non-agricultural, industrial uses. Continued registrations of nabam products for terrestrial food uses where tolerances need to be established require chronic feeding studies in both rodent and non-rodent species. If chronic studies are conducted to support the food uses of nabam, the 90-day feeding study for agricultural and domestic non-food uses would not be necessary.

   Dermal Studies. No adequate subchronic dermal studies (21-day or 90-day) are available for review. Because of the potential for accidental or incidental human exposure during the application of nabam, a subchronic dermal study (21-day) is required to support the continued registration of all uses of nabam.

   Inhalation Studies. There is no adequate subchronic inhalation toxicity study for nabam. This study is normally required to support the continued registration of products which consist of, or whose uses result in an inhalable material such as a gas, volatile substance, or aerosol. The Agency is reserving this requirement for nabam products applied as sprays, or having the potential for inhalation exposure, pending the result of an acute inhalation study to determine if repeated exposure is at a concentration likely to be toxic.

3. Chronic Testing

Chronic Toxicity Studies. There are no adequate studies defining long-term effects of nabam administration. These studies are not required to support the registration of products for non-food uses. For those nabam products registered for use on food crops, use directions generally specify application as part of an aqueous solution which includes zinc sulfate. The zinc displaces the sodium in nabam to form zinc ethylene bisdithiocarbamate (zineb). Therefore, it is not evident what material or mixtures of materials should be tested. An additional consideration is that one of the major metabolites of nabam and the other EBDC pesticides, ETU, has been demonstrated to have toxic effects (including oncogenicity) to the thyroid. It is not certain what effects the presence of zinc would have with respect to the formation of ETU or the rate at which ETU could be absorbed in the digestive tract. The requirement for long-term feeding studies to support the registration of products for food use would require preliminary studies to determine what material should be tested.

Oncogenicity Studies. No studies assessing the oncogenicity of nabam in rodents are available. Oncogenicity testing is required to support each manufacturing-use product if the active ingredient or any of its metabolites is structurally related to a recognized carcinogen, causes mutagenic effects or produces in subchronic studies a morphological effect in any organ that may lead to a neoplastic change.

At this time, the Agency believes that the potential of human exposure to nabam or its major metabolite, ETU, is negligible from the use of nabam in most industrial settings. The chemical is sold as ready-to-use formulations in bulk containers and applied by trained and experienced applicators. The labeling requires protective clothing when handling nabam including gloves, face shields, coveralls, and boots. For the most part, application is made using automatic metering systems. In those situations where nabam is applied by hand (such as with a cup or small container) protective clothing serves to eliminate significant exposure.

EPA lacks data on exposure to nabam from the metalworking fluid and tanning uses. The Agency is requiring additional chronic data and information on exposure to nabam for these, and other industrial uses.

To support registrations of products for use on food and agricultural and domestic non-food uses, oncogenicity studies on nabam (or a mixture of nabam and zinc sulfate) are required.

Teratology Studies. There are no adequate teratogenicity studies on nabam. Because of indications that ETU is teratogenic, studies are required on two mammalian species (preferably the rat and rabbit) to support all registered nabam uses.

Reproduction Studies. There are no adequate reproduction studies on nabam. Based on the limited and primarily dermal human exposure potential, a two-generation reproductive study is not required for industrial uses. This study is, however, required to support the continued registration of nabam products registered for use on food crops and agricultural and domestic non-food uses.

Mutagenicity Studies. A number of mutagenicity studies with nabam have been recently submitted and reviewed by the Agency. An Ames reverse mutation assay on Salmonella was conducted and no mutagenic response was observed in the absence of S9 activation. However, unacceptably high spontaneous background mutation frequencies occurred in two of five tested strains with rat and mouse S9 activation. The assay results were, therefore, considered questionable and the study must be repeated.

Male mice innoculated with S. typhimurium strain TA1530 were orally dosed with a solution containing 30% nabam. Under the conditions of the assay, a mutagenic response was not induced in the target bacterial cells. This study is acceptable.

In a Chinese hamster ovary (CHO) cell forward mutation assay, the test material did not induce a mutagenic response with or without mouse S9 activation. However, with rat S9 activation there was a significant increase in the mutation frequency at the highest dose tested. Since the effect occurred at a moderately cytotoxic level, higher doses should have been assayed to determine whether the response was valid or artifactual. This study is inconclusive and must be repeated.

In a sister chromatid exchange (SCE) assay in CHO cells, nabam did not induce a genotoxic response at four activated, cytotoxic doses. In the presence of rat and mouse S9 activation, significant increases in sister chromatid exchanges were observed at higher dose levels and nabam is presumed to be positive for genotoxicity. However, this study is inconclusive because moderate to marked mitotic delays, as indicated by a considerable number of first division metaphases, were observed at most of the dose levels of nabam under both activated and nonactivated conditions. This study must be repeated using lower dose levels and longer cell exposure times than in the previously submitted study.

An *in vivo* bone marrow cytogenetic assay was conducted. Under the conditions of the assay, the acute or subacute oral exposure of male rats to nabam did not cause a clastogenic response. In the acute part of the study, a Maximum Tolerated Dose (MTD) was not demonstrated. Therefore, the acute study is unacceptable and must be repeated at a sufficiently high dose of nabam to elicit a toxic or cytotoxic effect. The subacute study is acceptable and does not need to be repeated.

In a transformation assay, nabam with S9 activation, did not induce neoplastic transformation in C3H-10T 1/2 cells; a cytotoxic effect was achieved at the highest dose. In the presence of rat S9 activation there was no increase in the number of transformed foci; however, the highest dose of nabam tested was not cytotoxic. Therefore, the nonactivated study is acceptable and the rat S9 activated study is determined to be unacceptable.

Nabam did not exhibit promoter activity at the single dose evaluated in the cell transformation assay for promotion. Since it is possible that nabam was not assayed at an effective level, the study is unacceptable and should be repeated in a more appropriate cell line.

In an unscheduled DNA synthesis (UDS) assay, a significant increase in mean net nuclear grain counts was seen in primary rat hepatocytes exposed to the highest non-cytotoxic dose (5.0 ug/ml) of nabam. Increased UDS activity occurred at levels below 5.0 ug/ml as well as at 10 ug/ml. At doses above 10 ug/ml, there was no cell survival. Nabam is presumed to induce UDS, but the study is classified as inconclusive and must be repeated.

Since the results of most of these assays are inconclusive and must be repeated, a decision on the mutagenic potential of nabam cannot be made at this time.

4. Metabolism Studies. The Agency has conditionally accepted, pending the submission of further information on the study, a rat metabolism study demonstrating that both by oral and intravenous administration more than 90% of the total ^{14}C was excreted in urine and feces over the next 168 hours (7 days), with most of this excretion occurring in the initial 24 hours.

A high proportion of the radioactivity excreted both in urine and feces was tentatively identified as ethylene thiourea (ETU). In the feces, the ETU fraction was highest (>40% total ^{14}C) in rats dosed with 100 mg/kg nabam.

Seven days after administration, less than 0.01% of total ^{14}C activity was associated with the thyroid in any of the dose groups. In terms of the mass of the thyroid organ, there were fairly high concentrations of ^{14}C, with the highest mean of 20 ppm equivalents in the thyroid of males receiving a 100 mg/kg oral dose of nabam.

Further information on the rat metabolism study discussed above must be submitted.

5. Special Studies

Domestic Animal Safety Studies.

The registered uses of nabam are such that under normal circumstances and correct handling no significant exposure involving domestic animals is anticipated. No data on domestic animal safety are required.

Nabam Dermal (Percutaneous) Absorption/Penetration Studies.

Mixtures of ^{14}C-labeled and unlabeled nabam were applied at 0.1, 1 and 10 ug/rat in constant dosage volumes of 50 ul to approximately 4.9 cm^2 of rat skin. The rats were sacrificed at 0.5, 1, 2, 4 and 10 hours, and measurements of ^{14}C activity were made for blood, urine, feces, skin and water from washing of skin. The results of this study indicate that at least 0.3% of a 0.1 mg application is absorbed in the 10 hours following application. There is considerable uncertainty as to the upper limit, and the mean amount of ^{14}C not accounted for was 11%. Because the industrial use patterns will result in only negligible exposure, additional data are not required now. However, if new uses would result in significant dermal exposure or agricultural food uses are reinstated, then further work would be required to determine whether and at what rate the nabam bound to the skin continues to be absorbed after 10 hours and whether bioaccumulation occurs.

Human Studies.

There are no human data on the potential effects of nabam.

Toxicological Studies - ETU. Since ETU, a contaminant, degradation product, and metabolite of nabam and other EBDC products, presents toxicological concerns, available data on ETU were considered in the overall evaluation of nabam. These data are summarized, as follows:

1. Subchronic Studies. During a 90-day rat feeding study with mancozeb, an additional group of animals received 250 ppm ETU. Compound-related effects in this group were generally comparable to those observed at 1000 ppm mancozeb (depressed body weight and changes in hormone levels accompanied by diffused hyperplasia of thyroid follicular epithelium). Residue analysis for ETU in mancozeb-treated animals revealed none in blood.

   In a rat study conducted to examine the subchronic effects of ETU on the thyroid, levels of 50, 100, 500 and 750 ppm were fed for 30, 60, 90 and 120 days. A NOEL was not determined in this study due to effects of ETU seen on thyroid weights at all dosage levels at 120 days. In a second rat study levels of 0, 1, 5, 25, 125, and 625 ppm were fed for 30, 60, and 90 days. Thyroid hyperplasia, decreased uptake of ^{125}I by the thyroid, and decreased serum T_3 (triiodothyronine) and T_4 (tetraiodothyronine) were seen. The LEL was 25 ppm for the effects with 5 ppm (0.25 mg/kg) considered the NOEL.

   In a 90-day mouse study, ETU fed at levels of 0, 1, 10, 100, and 1000 ppm resulted in increased thyroid weights in females and an increased incidence of follicular cell hyperplasia in both sexes at levels of 100 ppm and higher. Liver toxicity was only observed at the highest level, 1000 ppm.

   In a 21-week study in Rhesus monkeys, at dosage levels of 0, 2, 10, 50 and 250 ppm ETU, serum thyroid hormone concentrations were measured as well as iodine uptake in the thyroid. Mild to moderate pituitary hypertrophy was seen at 50 and 250 ppm, as well as thyroid follicular lining cell hypertrophy and hyperplasia (mild at 50 ppm; moderate to severe at 250 ppm). Serum levels of T_4 (tetraiodothyronine) were significantly decreased in the 250 ppm group. Free serum T_4 levels were also significantly decreased in both the 50 and 250 ppm group; iodine uptake was significantly increased at these levels and thyroid stimulating hormone (TSH) levels were significantly increased at 250 ppm.

   In a 6-month Rhesus monkey study, at dosage levels of 0, 50, 150, and 450 ppm ETU, pituitary as well as thyroid hormone levels were measured. A NOEL was not demonstrated.

2. Oncogenicity Studies. Three oncogenicity studies have been reviewed, as discussed below:

   In a mouse study (Innes), two hybrid strains of mice were used: (C57BL/6 x C3H/Anf)F_1 [Strain X] and (C57BL/6 x AKR)F_1 [Strain Y]. Eighteen mice per sex per group were used in the treatment group. Only one dose was tested which was stated to be the maximum tolerated dose. When the mice were 7 days old, 215 mg/kg ETU was given by stomach daily. At 28 days of age, the mice were given diets containing 646 ppm of ETU. The mice were sacrificed after a total of 83 weeks of treatment. Histopathology consisted of examination of all major organs and of all grossly visible lesions. Thyroid glands were not examined. The incidence of liver tumors, which were not classified as adenomas or carcinomas but only as hepatomas, is outlined in the following table:

	Male		Female	
	Control	Treated	Control	Treated
Strain X	3/14	14/16	0/18	18/18
Strain Y	1/18	18/18	0/18	9/16

Totals: Controls - 4/68 Treated - 59/68

In a study with Charles River CD rats, 175 or 350 ppm ETU was administered in the diet for 18 months. At that time, 5 rats/sex were sacrificed and the remaining rats were placed on control diets until termination of the study at 24 months. The control group consisted of 32 male and 32 female rats. No thyroid lesions were seen in the control group. The incidence of thyroid lesions in the ETU-treated rats is presented below. The number of animals examined was not given.

	350 ppm		175 ppm	
Lesion	Males*	Females	Males	Females
Thyroid carcinoma** (follicular)	17	8	3	3
Thyroid solid cell ademona	0	1	0	2
Hyperplastic goiter	17	13	9	6
Simple goiter	2	4	4	2

* All five male rats in the high dose group sacrificed at 18 months had hyperplastic goiter; 3 had follicular thyroid cancer.

** Two with lung metastases.

In a two-year study, Charles River rats were placed on diets containing 0, 5, 25, 125, 250 or 500 ppm ETU. Body weight gain was adversely affected at the highest dose tested at 18 and 24 months for both males and females. ^{131}I uptake was statistically increased in male rats at 18 months in the 25 and 125 ppm groups and decreased at 500 ppm. At 24 months in the male rats, ^{131}I uptake was significantly increased in the 5 ppm group and decreased in the 500 ppm group. Because of large variability in the values obtained, there were not statistically significant differences in ^{131}I uptake in female rats.

Histopathology incidence data were combined for males and females. An increase in the number of rats with cataracts/keratitis and with thyroid follicular adenocarcinoma/carcinoma was observed in the groups fed 250 ppm and 500 ppm ETU; with thyroid adenomas in the 250 ppm group; and with thyroid hyperplasia in the 5, 25, 125 and 250 ppm groups. The LEL is 5 ppm (0.25 mg/kg/day) for the effects of ETU on the thyroid in this study. Relevant data are summarized as follows:

Tumor incidence data for rats, including 18-month interim sacrifice, fed ETU in the diet

	Dose levels in ppm					
	0	5	25	125	250	500
Pathological lesions						
Cataracts/keratitis	2	1	0	2	6	12
Thyroid carcinoma/ adenocarcinoma (follicular)	2	2	1	2	16	62
Thyroid adenomas	2	-	5	1	21	3
Thyroid hyperplasia	4	20	41	44	27	3
Parathyroid hyperplasia	6	11	8	2	3	0
Number of rats per group	72	72	73	73	69	70

Statistics were not reported on the histopathological data. Historical control data were not available. More detailed information on this study is not available.

3. Teratology Studies. ETU has been shown to be a teratogen in studies with rats and hamsters. In rats, it produces a wide variety of anomalies in the central nervous, urogenital and skeletal system as well as other organs at dosages that do not produce maternal or fetotoxicity. The NOEL for these effects is 5 mg/kg. Administration of T_3/T_4 with ETU to pregnant rats appears to reduce the incidence of some of these effects.

4. Mutagenicity Studies. Results of short-term assays indicate that ETU is weakly genotoxic; ETU has been shown to give mixed results for gene mutation in both bacterial and mammalian cell lines, but positive results for DNA repair in human cells, yeast and bacteria. Although reportedly positive in one mammalian cell transformation assay using hamster cells, an adequate assay in mouse cells was negative.

   The negative studies submitted for in vitro mammalian cell transformation/promotion for both mancozeb and ETU were judged unacceptable because the assays were conducted at only one dose, which may have been insufficient to conclude the test materials were not in vitro promoters. An in vitro mammalian cell transformation/promotion assay

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   The negative studies submitted for in vitro mammalian cell transformation/promotion for both mancozeb and ETU were judged unacceptable because the assays were conducted at only one dose, which may have been insufficient to conclude the test materials were not in vitro promoters. An in vitro mammalian cell transformation/promotion assay to address whether ETU has promoter (non-genotoxic) activity is required.

5. Metabolism Studies. In a study with Rhesus monkeys, 50 percent of an administered dose of ^{14}C-ETU was excreted in the urine within 24 hours and 90 percent within 72 hours. Only 0-0.68 percent of the label was eliminated in the feces at 24 hours and no radioactivity was found in the feces at the 48 and 72 hour sampling periods.

   In another study with Wistar rats, ^{14}C ETU was predominately excreted in the urine. The ratio of urine to fecal excretion varies with dose, i.e., for 0.1 ppm ETU, the ratio was 55/25, at 10 ppm ETU, the ratio was 70/10. Minimal radioactivity was recovered as $^{14}CO_2$ ($\leq$0.5 percent). The level of radioactivity plateaued in the thyroid gland after 8 days of dosing and declined rapidly once dosing was terminated.

6. Structure Activity Information. ETU is structurally related to thiourea, methimazole, propylthiouracil, and thiouracil; all of which are thyroid inhibitors. Chronic studies on thiourea in rats have shown that it induces hepatomas and thyroid enlargement. Methimazole, propylthiouracil and thiouracil all induce thyroid tumors in rats. Propylthiouracil also induces thyroid tumors in hamsters and guinea pigs and pituitary adenomas in mice. Thiouracil induces hepatomas and thyroid tumors in mice.

Risk Assessment. The Agency does not have any oncogenicity data on nabam. However, based on the data available on ETU, as discussed in the preceding section, the Agency has classified ETU, in accordance with the Agency's Guidelines for Carcinogen Risk Assessment (September 26, 1986, 51 CFR 33992) as a Group B2 oncogen, Probable Human Carcinogen.

The Agency's classification of ETU was made in accordance with its guidelines for carcinogen risk assessment. These guidelines categorize the evidence on carcinogenicity of chemicals in terms of how likely it is that the chemical is a human carcinogen. Under this scheme, a Group B2 categorization is appropriate if there is "sufficient evidence" of a THE chemical's carcinogenicity from animal studies. "Sufficient evidence" is defined as an increased incidence of malignant tumors (or combined malignant and benign tumors) in multiple species or strains, in multiple experiments, or to an unusual degree with regard to incidence, site or type of tumor, or age at onset.

ETU induced an increased incidence of thyroid adenomas and adenocarcinomas in two separate studies with rats and of hepatomas in two strains of mice. Furthermore, ETU induced the thyroid tumors in rats after one year or less of treatment and induced both the thyroid tumors in rats and hepatomas in mice to an unusual degree in a single experiment.

The classification as a Group B2 oncogen is also supported by positive structure-activity data since several other thyroid inhibitors (i.e., thiouracil and thiourea) have been found to induce hepatomas and/or thyroid tumors in rodents.

EPA acknowledges that the studies considered in arriving at its classification of ETU were not carried out in accordance with EPA guidelines for oncogenicity studies. EPA, however, does consider the studies adequate to conclude that ETU is oncogenic to rats and mice due to the magnitude of the response seen. The Agency's conclusions regarding the classification of ETU will be reconsidered when results of additional studies on ETU are available.

Worker and Dietary Exposure and Risk. At this time, the Agency believes the potential of human exposure to nabam or its major metabolite, ETU, is negligible from the use of nabam in most industrial settings. The Agency is requiring additional data and information on exposure to nabam in industrial use settings. The Agency will re-examine its position regarding human exposure from industrial use of nabam following receipt and review of the data and information requested.

All field or food crop uses of nabam pesticide products are currently suspended and the registered nabam technical products are prohibited from being formulated into pesticides for use on field or food crops. There should be no dietary exposure to nabam from commodities currently processed from these field or food crops. If nabam agricultural uses are reinstated, the result may be an increased dietary exposure to ETU, which because of exposure attributable to use of another EBDC pesticide, mancozeb, already presents concern. The use of nabam in sugar beet flume water is considered a food use and possible source of dietary exposure to nabam. There are no data available to assess the potential dietary exposure and resulting risk from this use. However, any exposure to ETU from such use would compound exposure levels. Additional chronic toxicology and residue data are required to support the registrations of nabam products for use on all food

C. OTHER SCIENCE FINDINGS

Environmental Fate. Available data are insufficient to fully assess the environmental fate of nabam. Data as set forth in Table A are either required or reserved pending further evaluation. The supplementary information discussed below is provided from studies that did not fulfill the data requirements for registration and must be repeated:

Groundwater. Studies submitted in response to the 1984 Data Call-In Notice gave only inconclusive results. However, these studies do indicate that the major degradate, ETU, has the potential to leach. Due to lack of an analytical method specific for ETU, no data are available that confirm ETU actually is in groundwater. Additional data are required to fully assess the potential of nabam and ETU to contaminate groundwater.

Ecological Effects. Available data are insufficient to completely evaluate the ecological effects of nabam. Data, as set forth in Table A, are either required or reserved pending further evaluation. The following conclusions can be made based on available data:

1. Toxicity to Birds. Available avian dietary studies were sufficient to assess the subacute toxicity of nabam to birds. The studies showed LC_{50} values for the mallard duck and bobwhite quail of greater than 5000 ppm active ingredient indicating that nabam is practically non-toxic to birds from dietary exposure.

2. Toxicity to Fish, Aquatic Invertebrates, and Estuarine/Marine Organisms. Data on representative products containing a mixture of 15% nabam and 15% sodium dimethyl dithiocarbamate indicate moderate toxicity to freshwater fish such as rainbow trout and moderate to high toxicity to estuarine organisms such as sheepshead minnow, American oysters, and grass shrimp.

3. Risks to Nontarget Organisms (Including Endangered Species). The Agency has assessed the risks, based on available data, from the uses of nabam. A discussion of this assessment follows.

    a. Terrestrial Organisms. Exposure of terrestrial vertebrates to nabam may occur when these organisms seek refuge or consume prey or water from aquatic sites adjacent to facilities utilizing nabam. These aquatic sites may be holding ponds or streams, rivers, estuaries, and lakes receiving discharge directly from the installation or holding pond. Available toxicity data for avian and mammalian species do not indicate a hazard.

Terrestrial vertebrates as well as invertebrates may be exposed to nabam when used as a fungicide on ornamentals. Residues that animals would be exposed to are expected to be significantly below the levels indicated in studies where toxicity would occur. Therefore, no hazard is associated with this use for terrestrial organisms.

b. Aquatic Organisms. Freshwater and marine organisms may be exposed to nabam from the aquatic non-food uses (process waters from pulp mills, cooling towers). Environmental levels of nabam are expected to diminish downstream of treatment plant discharges. However, the amount will vary with the treatment process and the ratio of the receiving body to the volume of the discharge. Although a 200 fold dilution generally occurs, thus eliminating the acute hazard to the most sensitive species, the potential for an extended acute (greater than 96 hours) or chronic effect may occur. Secondly, the acute and chronic toxicity of ETU has not been determined.

Additional use information is required including the location of facilities using nabam as well as aquatic residue monitoring at representative sites. A final hazard assessment will be done upon receipt and review of these data.

c. Endangered Species. There is inadequate information to consider if the continued use of nabam poses a threat to endangered species. Based on the avian toxicity data available on technical nabam and the current use rates, no ecological effects concerns have been identified at this time including concerns for endangered species. Additional use and monitoring data described above will be used to determine if the use of nabam is a threat to any endangered species.

Reentry Considerations. Toxicity and exposure criteria are set forth in 40 CFR 158. If a chemical meets the specified criteria, reentry data are required.

Nabam does not meet the acute toxicity criteria, and there is no epidemiological evidence that residues of this pesticide cause adverse effects on persons entering treated sites. However, ETU has demonstrated evidence of oncogenicity, mutagenicity, teratogenicity and thyroid effects. Therefore, the chronic toxicity criteria have been met. Nabam also meets the exposure criteria in that it is registered (although currently suspended) for use on crops which may involve substantial exposure to residues of the pesticide. Reentry data are required.

Product Chemistry. The Agency has evaluated the available data which identify the ingredients, materials, and manufacturing process and discuss the physical and chemical properties of nabam. All product chemistry data must be submitted for each technical nabam product. Some additional product chemistry data are required and some data previously submitted needs to be updated. These requirements are presented in Data Tables A and B.

D. TOLERANCE REASSESSMENT

There are no established tolerances for residues of nabam per se on any food or feed items. All food crop uses of nabam are currently suspended. When used on food crops nabam is tank mixed with zinc sulfate leading to the formation of zineb. Nabam is not mixed with zinc sulfate when used on onions to control smut. Therefore, for this use registrants are required to submit residue data on nabam. For the other food crop uses, application actually consists of a solution of zineb instead of nabam. Therefore, residues in agricultural commodities treated with nabam are expected to be zineb.

The use of nabam as an industrial biocide to treat flume water in sugar beet mills is considered to be a treatment of a raw agricultural commodity. Regulations have been established by the Food and Drug Administration under 21 CFR 173.320(b)(3) for nabam residues following application to sugar mill grinding, crusher and/or diffuser systems. The treatment of flume water, transporting and washing systems are under EPA's jurisdiction. Residue data are required in this Standard to determine if the residues concentrate in any of the processed sugar commodities.

Residue Data. Residue data for nabam, ETU, and any other residues of concern in sugar beets following a water treatment in the flume water transporting and washing system are required. A registered formulation of nabam should be applied at the maximum use rate for the system. Also, a processing study employing sugar beets containing measureable residues of nabam with subsequent analysis of dehydrated pulp, molasses, and refined sugar for nabam, ETU and any other residues of concern is required.

Toxicology Data: The toxicology data for nabam are insufficient to determine an Acceptable Daily Intake (ADI) and do not allow a decision as to whether the toxicity observed in the studies is due to nabam or ETU.

There are no data available to determine either a Provisional Acceptable Daily Intake (PADI) or Acceptable Daily Intake (ADI) for nabam.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on the review and evaluation of all available data on nabam, the Agency has made the following determinations. Where it is the Agency position that label revisions are needed in order for a product to remain in compliance with FIFRA, specific language will be set forth in Section D of this Chapter.

1. EPA is currently evaluating the potential human health risks resulting from the food, field and food crop and terrestrial non-food uses of nabam to determine whether additional regulatory action is warranted on nabam and the other EBDC pesticides containing the common contaminant, degradation product, and metabolite, ETU.

   Rationale: The EBDC's were placed in Special Review in 1977 based on the presumption that the EBDC's and ETU posed potential risks to human health or the environment. The Special Review was concluded in 1982 and the EBDC's were returned to the registration process. The Special Review issues and the Agency's decisions are discussed in the Background section of this document.

   ETU, a contaminant, degradation product, and metabolite of all the EBDC's, is mutagenic, oncogenic and teratogenic, and the Agency has classified it as a Group B2 oncogen (Probable Human Carcinogen). See the Agency Assessment section of this Standard for a discussion of the classification of ETU.

   Nabam is currently used for certain food uses in industrial settings. While the Agency lacks information enabling it to quantify dietary exposure to nabam or ETU from such uses, any increase in ETU exposure would add to a level already presenting concern to the Agency due to that resulting from the use of mancozeb. The nabam products registered for use on field or food crops and terrestial non-food uses are currently suspended. However, if these uses were reinstated the use would result in additional dietary and applicator exposure to nabam and ETU. Any level of ETU residue would, in the case of dietary risk, increase overall exposure to ETU above the levels resulting from mancozeb, which themselves present concern to the Agency.

2. The Agency does not believe that further regulatory action on nabam products registered for most industrial non-food uses is warranted at this time.

   Rationale: ETU, a contaminant, degradation product and/or a metabolite of all the EBDC's, is mutagenic, oncogenic and teratogenic, and the Agency has classified it as a Group B2 oncogen (Probable Human Carcinogen). See the Agency Assessment section of this Standard for a discussion of the classification of ETU.

   After considering exposure to ETU from the industrial, non-food uses of nabam as discussed in the preceding Agency Assessment section, the Agency believes that the risks from exposure to ETU from most industrial uses of nabam are not a concern at this time because applicator exposure, based on available information, appears negligible. Additional information is being required to assess exposure to nabam from the metalworking and tanning uses.

3. The Agency will not consider any new food use tolerances for nabam.

   Rationale: The current residue chemistry and toxicology data are not sufficient to assess existing and pending tolerances. The toxicology data base is insufficient to determine an ADI and also does not allow a decision as to whether observed toxicity is due to nabam or ETU. No new food uses will be considered until these issues are resolved.

4. The Agency will consider the need for establishment of tolerances for ETU and any intermediate metabolites when data are sufficient to permit such decisions.

   Rationale: The toxicology data base for nabam is insufficient to determine whether observed toxicity is due to nabam, ETU, or additional metabolites.

5. The Agency will not establish any food/feed additive regulations pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) and is deferring action on previously established food/feed additive regulations.

   Rationale: The Delaney Clause in Section 409 of the FFDCA bars the establishment of food additive regulations for substances which induce cancer in man or test animals, with certain exceptions. The Agency is currently developing a position relative to the Delaney Clause and FIFRA. Once this policy has been established, the Agency will determine what action is required in relation to pesticides which have produced positive oncogenic responses in chronic animal studies.

6. The Agency is specifying precautionary labeling pertaining to fish which must be added to the labels of all nabam products, in order to remain in compliance with FIFRA.

   Rationale: Based on available data, nabam has been demonstrated to be moderately toxic to fish. Because of its toxicity to fish, extending the warning language to cover all nabam products will serve to alert users about exposure to these organisms.

7. The Agency's position is that protective clothing labeling for nabam products, as stipulated in the 1982 Decision Document should be updated as noted herein in order to remain in compliance with FIFRA.

   Rationale. A major toxicological concern from exposure to nabam at this time is the hazard to the human thyroid from the degradation product, ETU, an acknowledged goitrogen, teratogen, and oncogen. Additional data are required to determine whether nabam also poses a teratogenic risk. Risks of teratogenicity and thyroid toxicity to commercial applicators can be adequately reduced by maintaining the requirement that protective clothing be worn while mixing, loading and applying the chemical; the same would appear true for agricultural mixers, loaders, and applicators, should agricultural uses resume.

8. The Agency has determined that all data will be immediately reviewed as they are submitted.

   Rationale: Because of the general concerns over ETU and the EBDC's, the Agency believes it is essential that all data be reviewed as they are received.

9. While data gaps are being filled, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing nabam as the sole active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new uses will not be registered. Registrants must provide or agree to develop and provide additional data, as specified in the Data Appendices, in order to maintain existing registrations.

   Rationale: Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary. The Agency has elected not to consider registration of any significant new uses while data gaps are being filled and data evaluated, based on its concerns for nabam and ETU as explained herein.

10. The Agency will continue to require that, in order to remain in compliance with FIFRA, the importance of observing the preharvest intervals be highlighted on labels of residential (homeowner) products. Language is specified herein.

Rationale. In the 1982 Decision Document, the Agency determined that, as a risk reduction measure to reduce human dietary exposure, preharvest intervals must be highlighted on residential labels so that home garden users will be encouraged to comply with them. Although the risks from dietary exposure to nabam cannot be fully assessed at this time, the Agency believes continuation of this emphasis as a risk reduction measure is warranted. Specific language has been chosen to emphasize to users the importance of adherence to the preharvest intervals.

11. The Agency is requiring reentry data for nabam. In order to remain in compliance with FIFRA, an interim 24-hour reentry interval requirement must be placed on the labels of all nabam end-use products registered for agricultural uses, until the required data are submitted and evaluated and any change in this reentry interval is announced.

Rationale. Nabam meets both the chronic toxicity and exposure criteria specified in 40 CFR 158.140 for reentry data. Until these data are received and evaluated, an interim 24-hour reentry interval will serve to reduce exposure of field workers to this chemical, should agricultural uses of nabam be reinstated.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain nabam as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard - To be registered or reregistered under this Standard, manufacturing-use products (MP's) must contain nabam as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1% and any N-nitroso compounds at greater than 1 ppm.

Acute Toxicity Limits - The Agency will consider registration of technical grade and manufacturing-use products containing nabam provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

Use Patterns - To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for registered uses as listed in the Use Index, Appendix III.

D. LABELING

All nabam products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

In order to remain in compliance with FIFRA, no pesticide product containing nabam may be released for shipment by the registrant after May 1, 1988, unless the product bears an amended label which complies with the specifications of this Standard.

In order to remain in compliance with FIFRA, no pesticide product containing nabam may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after May 1, 1989, unless the product bears an amended label which complies with the specifications of this Standard.

In addition to the above, in order to remain in compliance with FIFRA, the following information must appear on the labeling:

1. Ingredient Statement. The ingredient statement for MP's must list the active ingredient as:

   Nabam (disodium ethylene bisdithiocarbamate).....(%)

   Inert Ingredients..................................(%)

2. Use Pattern Statements. All manufacturing-use products must state that they are intended for formulation into end-use products only for acceptable use patterns. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Disposal Statements. Because nabam has not been designated as an acute or toxic hazardous waste under the Resource Conservation and Recovery Act (RCRA), the following is the appropriate pesticide disposal statement for nabam products:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

The labels of all products must bear the appropriate container disposal statement (See Appendix II).

3. Precautionary Statements

Manufacturing-Use Products

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

End-Use Products

a. Agricultural Use Products

"This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

All Home Use Products

> "PROTECTIVE MEASURES: Always spray with your back to the wind. Wear long-sleeve shirt, long pants, and rubber gloves. Wash gloves thoroughly with soap and water before removing. Change your clothes immediately after using this product and launder separately from other laundry items before reuse. Shower immediately after use."

Home Use Products with Food Uses

> "Preharvest intervals on this label are specified so that pesticide residues will be at an acceptable level when the crop is harvested."

All Agricultural Products

> "After (sprays have dried/dusts have settled/vapors have dispersed, as applicable) do not enter or allow

entry into treated areas until the 24-hour reentry interval has expired unless wearing the personal protective equipment listed on the label."

"WORKER SAFETY RULES

Keep all unprotected persons, children, livestock, and pets away from treated area or where there is danger of drift.

"Do not rub eyes or mouth with hands. See First Aid (Practical Treatment Section)."

"PERSONAL PROTECTIVE EQUIPMENT

HANDLERS (MIXERS, LOADERS, AND APPLICATORS) AND EARLY REENTRY WORKERS MUST WEAR THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT: a long-sleeve shirt and long pants or a coverall that covers all parts of the body except the head, hands, and feet; chemical resistant gloves; shoes, socks, and goggles or a face shield. During mixing and loading, a chemical resistant apron must also be worn.

During application from a tractor with a completely enclosed cab with positive pressure filtration, or aerially with an enclosed cockpit, a long-sleeve shirt and long pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and worn while exiting.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before eating, smoking or drinking. Always wash hands and arms with soap and water before using the toilet.

After work take off all clothes and shoes. Shower using soap and water. Wear only clean clothes. Do not use contaminated clothing. Wash protective clothing and protective equipment with soap and water after each use. Personal clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated or drenched with nabam must be destroyed according to state and local regulations.

HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

During aerial application, human flaggers are prohibited unless in totally enclosed vehicles."

b. Industrial Use Products

"This pesticide is toxic to fish. Spills, sprays, and runoff from use site may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

"HANDLE (INCLUDING MIXING, LOADING, OR APPLYING) THIS PRODUCT ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT: A long-sleeve shirt and long pants or a coverall that covers all parts of the body except the head, hands, and feet; chemical resistant gloves; and goggles or a face shield. During mixing and loading, a chemical resistant apron must also be worn."

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V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit, and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). **Please note**, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Lois A. Rossi, Product Manager (Team 21)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A and B contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[2]/	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All	No		Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No		Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No		Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No		Yes	12 Months
62-2 - Certification of Ingredient Limits	TGAI	All	No		Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	All	No		Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	Yes		Yes	6 Months
63-3 - Physical State	TGAI	All	Yes		Yes	6 Months
63-4 - Odor	TGAI	All	No		Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[2]	Timeframe for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-5 - Melting Point	PAI	All	No		Yes[3]	6 Months
63-6 - Boiling Point	TGAI	All	No		Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No		Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	No		Yes	6 Months
63-9 - Vapor Pressure	PAI	All	No		Yes	6 Months
63-10 - Dissociation constant	PAI	All	No		Yes	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	No		Yes	6 Months
63-12 - pH	TGAI	All	NA		No	
63-13 - Storage Stability	TGAI	All	No		Yes	15 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	NA	No		NA	

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[1] Composition: TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.

[2] Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

[3] The melting point of the solid material remaining after the removal of water is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[2]/	Timeframe for Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	No		Yes[3]/	6 Months
171-3 - Directions for Use		No		Yes	6 Months
171-4 - Nature of Residue[4]/ (Metabolism)					
- Plants	PAIRA	Partially	00088825,00088826, 00088833,00088831, 00097231,00088921	Yes[5]/	18 Months
- Livestock	PAIRA & Plant Metabolites	Partially	00088834,00088835	Yes[6]/	18 Months
171-4 - Residue Analytical Method					
- Plant residues	TGAI & Metabolites	Yes	00088826,00097051, 00041704,40065801, 00097051,00088891, 00088826,00159693, 00041704,00159693, 40118601,40065803, 40065802	Yes[7]/	15 Months
- Animal residues	TGAI & Metabolites	No		Yes[7]/	15 Months
171-4 - Storage Stability Data	TEP or PAI, & Metabolites	No		Yes[8]/	Approved protocol: 3 months Study: 18 months

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[2]/	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use[4]/					
171-4 - Magnitude of the Residue - Residue Studies					
o Crop 2, Sugar Beet - Flume Water					
-- Crop Field Trials	TEP	No		Yes[9]/	18 Months
-- Processed Food/Feed	EP	No		Yes[10]/	24 Months
-- Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	40118602	Reserved[11]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM
FOOTNOTES

§158.125 Residue Chemistry - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient; radiolabeled; TEP = Typical end-use product.

2/ Data must be submitted for individual tests no later than specified in Column 7(Timeframe for Submission).

3/ Refer to Product Chemistry Data Tables.

4/ Residue data are required to reinstate registration of any food crop use that is presently suspended. Currently suspended uses include: asparagus, beans(lima and snap), beets, swiss chard, broccoli, cabbage, cauliflower, cantaloupe, cucumber, squash, watermelon, carrots, celery, cherries(sour), citrus, corn(sweet), grapes, hops, kale and mustard greens, lettuce, onions, peppers, spinach. strawberries, tomatoes, turnips and wheat. Additional data are required reflecting residues of nabam in or on onions. The registrant must propose a tolerance for onions and submit data reflecting nabam, ETU, and other residues of concern resulting from application following the established use directions. Applications must be made using nabam alone without zinc sulfate. Tests must be conducted in OR(12%), NY(11%), CO(8%), TX(8%), CA(7%), ID(6%), and MI(6%) (state production figures follow abbreviations parenthetically) which represent states producing approximately 58% of the U.S. onion crop (Agricultural Statistics, 1983, p. 164). Use directions must be proposed and appropriate supporting data submitted for two additional group members (garlic and leeks or shallots).

5/ Studies are required indicating the uptake, distribution, and metabolism of nabam in food crops following soil application at planting. Sampling intervals through at least 21 days must be included. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate the terminal residues. Residue identities must be confirmed by a method such as GC, HPLC and/or mass spectrometry. Data reflecting solvent extract efficiency of nabam residues must also be represented.

6/ Metabolism studies are required utilizing ruminants and poultry. Animals must be dosed for 3 days with [^{14}C]nabam at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat.

7/ If the requested data regarding the Nature of the Residue in Plants and Animals reveal additional metabolites of toxicological concern, additional analytical methods for data collection and enforcement may be required.

8/ To support crop residue data, storage stability studies must be conducted on both weathered samples (nabam) and fortified frozen samples (nabam, metabolites and ETU) of one representative crop from each crop grouping (40 CFR 180.34) on which registered uses of nabam exist. Analyses of each crop must be conducted over a time period that includes the time interval that the raw agricultural commodity is held in frozen storage prior to the crop residue analysis. To support residue data on processed commodities, fortified storage stability data are required for all processing studies submitted to the Agency. Analyses must be conducted over a time period that includes the frozen storage of the raw agricultural commodity prior to processing and each processed commodity prior to the residue analysis. Protocols for these studies must be submitted to and approved by the Agency prior to initiating the studies.

(a) Storage stability data using weathered samples. Data are required on the parent compound, nabam, in which crop samples field treated with a typical end use product are frozen immediately upon harvesting. The integrity of the samples must be maintained by freezing. The samples must be analyzed for nabam on the day they arrive at the analytical laboratory, and then stored frozen and analyzed periodically for nabam during the time intervals specified in the Agency approved protocol.

(b) Storage stability data using fortified samples. Data are required on nabam, ETU, and metabolites in which a group of untreated samples of raw agricultural commodities and processed crops are fortified (spiked) with only nabam (pure active ingredient), another group of samples is fortified with only ETU, and other groups are fortified individually with each additional metabolite. Immediately after fortification, the samples fortified with nabam must be analyzed for nabam and ETU; samples fortified with ETU must be analyzed for only ETU; and samples fortified with other metabolites must be analyzed for only the metabolite with which the sample was fortified. Sample integrity must be maintained by freezing, and analyses for nabam, ETU, and metabolites must be conducted periodically during the time intervals specified in the Agency approved protocol.

(c) Storage stability data for livestock/poultry feeding studies. If cattle and poultry feeding studies are required (see footnote 11), fortified storage stability studies will be required on all animal commodities (i.e., tissues, milk and eggs) for which residue data are submitted to the Agency. Analyses must be conducted over a time period that includes the time interval that each commodity is held in frozen storage prior to residue analyses.

9/ Residue data must be submitted depicting nabam, ETU and any other residues of concern in sugar beets following a water treatment in the flume water transporting and washing system. A registered formulation of nabam should be applied at the maximum use rate for the system. Based on this data an appropriate pesticide tolerance level should be proposed under 40 CFR 180.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM
FOOTNOTES

§158.125 Residue Chemistry - Continued

10/ A processing study is required employing sugar beets containing measurable residues of nabam with subsequent analysis of dehydrated pulp, molasses and refined sugar for nabam, ETU and any other residue of concern. If residues are found to concentrate in any of the processed commodities, the Agency will assess the need for appropriate food/feed additive tolerances. However, final disposition of these food/feed additive tolerances would be dependent upon the Agency's position regarding Delaney Clause issues.

11/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the need for feeding studies depicting the magnitude of residues in animal products will be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]	Use Patterns[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[3]	Timeframe for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,D,H	No	--	Yes	9 Months
	ETU	A,B,D,H	No	--	Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B,D,H	No	--	Yes	9 Months
	ETU	A,B,D,H	No	--	Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No	--	Yes	9 Months
	ETU	A	No	--	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	--	No	--	Reserved[4]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,H	No	--	Yes	27 Months
	ETU	A,B,H	No	--	Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	--	Yes[5]	27 Months
	ETU	A	No	--	Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	No	--	Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No	--	Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,D,H	No	--	Yes	12 Months
	ETU	A,B,D,H	No	--	Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]/	Use Patterns[2]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[3]/	Timeframe for Submission
§158.130 Environmental Fate - Continued						
163-2 - Volatility (Lab)	TEP	A	No	—	Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No	—	Reserved[4]/	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP ETU	A,B A,B,	No No	— —	Yes Yes	27 Months 27 Months
164-2 - Aquatic (Sediment)	TEP	D	No	—	Yes	27 Months
164-3 - Forestry	TEP	—	NA	—	No	
164-5 - Soil, Long-term	TEP	A	No	—	Reserved[6]/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	—	Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	—	Reserved[7]/	
165-3 - Irrigated Crops	TEF	—	NA	—	No	
165-4 - In Fish	TGAI or PAIRA	A,B,D	No	—	Yes	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	A,B,D	No	—	Reserved[8]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

§158.130 Environmental Fate - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient; radiolabeled; TEP = Typical end-use product; ETU = ethylene thiourea.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted no later than indicated for individual tests (requirements).
4/ Data are reserved depending on results of volatility test.
5/ An anaerobic aquatic metabolism study may replace the anaerobic soil metabolism study.
6/ Deferred, pending the receipt of terrestrial field dissipation studies, Section 164-1.
7/ Deferred, pending the receipt of data from confined rotational crop studies Section 165-1.
8/ Deferred, pending the receipt of fish accumulation data, Section 165-4.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Date Requirement	Test Substance1/	Use Patterns2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,D,H	Yes	00121050	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,D,H	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,D,H	No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	A,B,D,H	No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI	A,B,D,H	No		Yes	9 Months
81-6 - Dermal Sensitization - Human	TGAI	A,B,D,H	Yes	00121050	No	
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,D,H	No		No9/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and - Nonrodent (Dog)	TGAI	A,B,D,H	No		Yes	15 Months
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,D,H	No		Yes	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B,H	No		Reserved4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]/	Use Patterns[2]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology - Continued						
82-4 - 90-Day Inhalation: - Rat	TGAI	A,B,H	No		Reserved[6]/	
82-5 - 90-Day Neurotoxicity:	TGAI	A,B,D,H	NA		NA[9]/	
- Hen						
-Mammal						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:						
- Rodent, and	TGAI	A,B,H	No		Yes[3]/[5]/	50 Months
	ETU		No		Yes[3]/[5]/8/	50 Months
- Nonrodent (Dog)	TGAI	A,B,H	No		Yes[3]/[5]/	50 Months
	ETU		No		Yes[3]/[5]/	50 Months
83-2 - Oncogenicity - 2 species:						
- Rat (preferred), and	TGAI	A,B,H	No		Yes[3]/[5]/	50 Months
- Mouse (preferred)	TGAI	A,B,H	No		Yes[3]/[5]/	50 Months
83-3 - Teratogenicity - 2 species:						
- Rat	TGAI	A,B,D,H	No		Yes	15 Months
- Rabbit	TGAI	A,B,D,H	No		Yes	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]	Use Patterns[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology - Continued						
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,H	No		Yes[3]	39 Months
	ETU		No		Yes[3]	39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,D,H	Partially	00153559,00152701, 00152702	Yes[11]	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A,B,D,H	Partially	00152700,00152699	Yes[12]	12 Months
84-4 - Other Mechanisms of Mutagenicity	TGAI	A,B,D,H	Partially	00151955,00151954	Yes[10]	12 Months
	ETU	A,B,D,H	No		Yes[10]	12 Months
SPECIAL TESTING						
85-1 - General Metabolism Rat	PAI or PAIRA	A,B,D,H	Yes	00160825	No	
85-2 - Domestic Animal Safety	Choice		No		No	
85-3 - Percutaneous Absorption - (rat)	PAIRA	A,B,D,H	Partially	00156613	Yes[7]	6 Months
- Human Exposure Studies	As Appropriate	IP	No		Yes[13]	6 Months

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[1] Composition: PAI = Pure active ingredient; ETU = Ethylene thiourea; PAIRA = Pure active ingredient radiolabeled; Choice = Choice of several test substances determined on a case-by-case basis; TGAI = Technical grade of the active ingredient.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor; IP= Industrial preservative (including metal cutting fluid and tanning uses).

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

§158.135 Toxicology - Continued

3/ Study or studies are required to support registrations of nabam-containing products involving use on food, field or food crops and terrestrial non-food uses. Preliminary studies to determine the material to be tested (i.e., nabam or nabam mixed with an aqueous solution including zinc sulfate in which zinc replaces the sodium in nabam to form zineb) are required.

4/ The requirement for a 90 day dermal study depends upon the outcome of the 21 day dermal study and upon application rates.

5/ Registrants who conduct chronic feeding and/or oncogenicity studies should inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the Maximum Tolerated Dose observed in subchronic or range finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being used in the chronic feeding and/or oncogenicity studies. If EPA subsequently determines that the study was conducted using a dosage rate that was too low to assess long-term effects, the study may be deemed not to satisfy the data requirement.

6/ Required if use may result in repeated inhalation at a concentration likely to be toxic.

7/ Although the study is acceptable, additional information is required to give more precise measurement of the amount on nabam absorbed and bound to the skin. For field and food uses and terrestrial non-food uses, a study determining the maximum rate of absorption of ETU is required. Registrants must discuss the protocol with the Agency prior to the commencement of the study.

8/ In the chronic studies, there must be emphasis on reporting of possible neurologic effects (both from in-life observation and histologic examination). In the chronic rodent study, additional animals must be utilized that would allow performance of in situ neurological examinations.

9/ Not required. (Nabam is not an organophosphate).

10/ A mammalian cell transformation assay on nabam and ETU, with or without metabolic activation, in one of the following viral cell cultures capable of detecting enhancement of transformation by chemicals (promotion): Syrian hamster embryo cells infected with simian adenovirus, or Fischer rat embryo cells infected with Rauscher leukemia virus, or nouse embryo cells infected with AKR (mouse) leukemia virus.

11/ The following data are required: Ames reverse mutation in *Salmonella* with rat and mouse S9 activation; and Chinese Hamster Ovary (CHO) cell forward mutation assay with rat S9 activation.

12/ The following data are required: sister chromatid exchange (SCE) assay in CHO cells using lower dose levels and longer cell exposure times than in the previously submitted study.

13/ For each registered use (testing material and design of study will depend on particular use), testing protocols are to be submitted no later than 90 days from the date of the registrant's receipt of this Standard. The data must be submitted no later than 6 months after the protocol review has been completed.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,H	No		Yes[1]/[2]/	27 Months
132-1 - Soil Dissipation	TEP	A,B,H	No		Yes[2]/	27 Months
133-3 - Dermal Exposure	TEP	A,B,H	No		No[3]/	27 Months
133-4 - Inhalation Exposure	TEP	A,B,H	No		No[3]/	27 Months

1/ Dislodgeable residue studies must be conducted on one field grown variety of cut flowers and a glass house grown variety. These studies must be capable of identifying both the parent compound and its breakdown product, ethylene thiourea (ETU), at least at the established NOEL levels.

2/ Dislodgeable residue studies must be conducted on one field grown food crop should the registrants request that any of the currently suspended food crop uses be restored. These residue studies must be capable of identifying both the parent compound and the ethylene thiourea at levels safely below the established NOEL levels.

3/ Human-exposure monitoring data may be submitted, if the registrant wishes to use the "allowable exposure method" of determining reentry intervals. The data submitted are limited to foliar and soil dissipation studies, human exposure (and reentry intervals) would be estimated from dislodgeable residues as explained in Subdivision K of the Guidelines. If exposure studies are submitted, both dermal exposure and inhalation exposure must be submitted. Exposure data and information are being required for the industrial uses of nabam under a separate Data Call-In Notice.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]	Use Patterns[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[3]	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,D,H	No		Yes	9 Months
71-2 - Avian Dietary Toxicity	TGAI	A,B,D,H	Yes	00022923	No	9 Months
	ETU	A,B,D,H	No		Reserved[11]	
71-3 - Wild Mammal Toxicity	TGAI	A,B,D,H	No		No	
71-4 - Avian Reproduction	TGAI	A,B,D,H	No		Yes[10]	18 Months
	ETU	A,B,D,H	No		Reserved[12]	
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,D,H	No		No	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,D,H	No		Yes	9 Months
	TEP[4]	D	No		Yes	9 Months
	ETU	D	No		Reserved[8]/[13]	
72-2 - Acute LC_{50} Freshwater Invertebrate	TGAI	A,B,D,H	No		Yes[5]	9 Months
	TEP[4]	D	No		Yes	9 Months
	ETU	D	No		Reserved[8]/[13]	
72-3 - Acute LC_{50} Estuarine and Marine Organisms						
- Fish	TGAI	D	No		Yes[5]	12 Months
	TEP[4]	D	Yes	107906	No	
	ETU	D	No		Reserved[8]/[13]	

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance1/	Use Patterns2/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?3/	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING - cont'd						
- Shrimp	TGAI	D	No	00107905	Yes5/	12 Months
	TEP	D	Yes	00097064	No	
	ETU	D	No		Reserved8/13/	
- Oyster	TGAI	D	No		Yes5/	12 Months
	TEP	D	No		Yes5/	12 Months
	ETU	D	No		Reserved8/13/	
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Freshwater	TGAI	D	No		Reserved6/	
	ETU	D	No		Reserved6/8/13/	
- Estuarine	TGAI	D	No		Reserved6/	
	ETU	D	No		Reserved6/8/13/	
72-5 - Fish Life - Cycle	TGAI	D	No		Reserved9/	
72-6 - Aquatic Organism Accumulation	TGAI	D	No		Yes	15 Months
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	D	No		Yes7/	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM
FOOTNOTES

§158.145 Wildlife and Aquatic Organisms - Continued

1/ TGAI = Technical grade of active ingredient; ETU = ethylene thiourea; TEP = Typical end-use product.

2/ A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Not required for industrial or ornamental uses.

4/ Typical end-use product is the mixture of 15% nabam and 15% sodium dimethyl dithiocarbamate.

5/ Required to support uses such as cooling towers, pulp mills, sugar refineries, and oil recovery processes where discharges into aquatic systems are likely to occur.

6/ Both fish and invertebrate life cycle data may be required to support such uses as cooling towers, pulp mills, sugar refineries, and oil recovery processes where discharges into aquatic systems are likely to occur. This requirement is dependent upon the results of the monitoring study.

7/ Monitoring of nabam in industrial effluents and receiving waters is be required where the pesticide is used as a biocide in cooling towers, pulp and paper mills, oil operations, as well as sugar refineries. Based on use information (i.e., geographic sites, amount used, etc.), the registrant is required to develop acceptable protocols (within 3 months) to sample a representative number of the above facilities. These studies are required to assess the release of nabam into the environment due to concern for endangered aquatic species and chronic effects to aquatic organisms. Any protocol developed for monitoring this chemical must meet the following requirements: (i) use of standard analytical methods, i.e., HPLC or MSGC, to measure nabam and the degradate ethylene thiourea, (ii) sites selected for sampling must be where nabam is currently being used and be representative of small and large facilities and/or volumes, (iii) sites selected must also be representative of (1) a range in volume of the receiving water bodies or rivers and (2) freshwater and estuarine ecosystems, (iv) samples taken for analysis must be taken before treatment, after treatment, and from receiving waters, (v) sampling should be done at regular intervals for a long enough period of time to account for such things as seasonal and use variations.

8/ ETU is the primary degradate of nabam. The material is water soluble and is persistent in soil and water beyond 4 days.

9/ Reserved pending the results of monitoring and data from fish early life stage and chronic invertebrate studies.

10/ Most agricultural uses call for multiple applications; therefore resulting in repeated exposure to birds.

11/ Pending the results of photolysis and hydrolysis studies there may be requirements for waterfowl and upland game bird studies.

12/ Pending results of avian reproduction studies on technical nabam and environmental fate data such as hydrolysis and photolysis.

13/ Reserved pending results of environmental fate data such as hydrolysis, photolysis, aquatic field dissipation studies on technical nabam.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]/	Use Patterns[2]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.150 Plant Protection						
121-1 - Target Area Phytotoxicity	TEP	D	No		No[3]/	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	D	No		No[4]/	
122-1 - Vegetative Vigor	TGAI	D	No		No[4]/	
122-2 - Aquatic Plant Growth	TGAI	D	No		Yes	9 Months
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	D	No		No[4]/	
123-1 - Vegetative Vigor	TGAI	D	No		No[4]/	
123-2 - Aquatic Plant Growth	TGAI	D	No		Reserved[5]/	
TIER III						
124-1 - Terrestrial Field	TEP	D	No		No[4]/	
124-2 - Aquatic Field	TEP	D	No		Reserved[6]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM
FOOTNOTES

§158.150 - Plant Protection - (Cont'd)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop, F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Whether data are required is determined on a case-by-case basis, where phytotoxicity issues may be involved.

4/ Use in cooling towers does not require submission of terrestrial phytotoxicity data.

5/ Reserved pending results of Tier I.

6/ Reserved pending results of Tier II.

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM

Data Requirement	Test Substance[1]/	Use Patterns[2]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey Bee Acute Contact Toxicity	TGAI	A,B,H	Yes	00036935	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B,H	No		No[3]/	
141-4 - Honey Bee Subacute Feeding Study	Reserved[4]/					
141-5 - Field Testing for Pollinators	TEP	A,B,H	No		No[3]/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[5]/					
142-2 - Aquatic Insect Life Cycle Study	Reserved[5]/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[5]/					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	Reserved[5]/					

TABLE A
GENERIC DATA REQUIREMENTS FOR NABAM
FOOTNOTES

§158.155 Nontarget Insect - (Cont'd)

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ As data from the acute contact study show low toxicity to honey bees, no further testing is required.

4/ Reserved pending development of test methodology.

5/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NABAM

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[2]/	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All			Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	All			Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All			Yes	12 Months
62-2 - Certification of Limits	MP	All			Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All			Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All			Yes	6 Months
63-3 - Physical State	MP	All			Yes	6 Months
63-4 - Odor	MP	All			Yes	6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NABAM

Data Requirement	Test Substance[1]/	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[2]/	Timeframe for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All			Yes	6 Months
63-12 - pH	MP	All			Yes	6 Months
63-14 - Oxidizing or Reducing Action	MP	All			Yes	6 Months
63-15 - Flammability	MP	All			Yes	6 Months
63-16 - Explodability	MP	All			Yes	6 Months
63-17 - Storage Stability	MP	All			Yes	15 Months
63-18 - Viscosity	MP	All			Yes	6 Months
63-19 - Miscibility	MP	All			Yes	6 Months
63-20 - Corrosion Characteristics	MP	All			Yes	15 Months
Other Requirements:						
64- 1 - Submittal of samples	NA	NA			No	

1/ Composition: MP = Manufacturing-use product.

2/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NABAM

Data Requirement	Test Substance[1]	Use Patterns[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,D			Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,D			Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B,D			Yes	9 Month
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,D			Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	A,B,D			Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B,D			Yes	9 Months

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[1] Composition: MP = Manufacturing-use product.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

II. LABELING APPENDICES

Summary of label requirements and table

40 CFR 162.10 Labeling Requirements

Physical/Chemical Hazards Labeling Statements

Storage Instructions

Pesticide Disposal Instructions

Container Disposal Instructions

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27963, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

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(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

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allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

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inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000.	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

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placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

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stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumfor use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five

(45) days from the date such notice is sent to submit evidence in rebuttal of the presumption: provided, however, that for good cause shown the Administrator may grant an additional sixty (60) days in which such evidence may be submitted.

(ii) At any time an applicant or registrant may petition the Administrator to withdraw his application or terminate his registration. The Administrator may, in his discretion, deny any petition for withdrawal or for termination and proceed in accordance with these regulations.

(2) *Rebuttal of Presumption.* The party seeking new or continued registration may rebut the presumption arising under paragraph (a)(1) of this section by sustaining the affirmative burden or proof set forth in paragraph (a)(4) of this section. After review of the evidence submitted in rebuttal of the presumption, the Administrator shall determine in accordance with paragraph (4) of this § 162.11(a) whether the applicant or registrant has sustained his affirmative burden and shall issue notice of such determination in accordance with paragraph (a)(5) of this section.

(3) *Risk Criteria.* A rebuttable presumption shall arise if a pesticide's ingredient(s), metabolite(s), or degradation product(s) meet or exceed any of the following criteria for risk, as indicated by tests conducted with the animal species and pursuant to the test protocols specified in the Registration Guidelines, or by test results otherwise available. In making this determination the Agency will take into consideration the type of effect, the statistical significance of the findings and whether the tests were conducted in accordance with the material requirements for valid tests as recognised by experts in the field.

(i) *Acute toxicity*—(A) *Hazard to Humans and Domestic Animals.* (*1*) Has an acute dermal LD_{50} of 40 mg/kg or less as formulated; or

(*2*) Has an acute dermal LD_{50} of 6 g/kg or less as diluted for use in the form of a mist or spray;

(*3*) Has an inhalation LC_{50} of 0.04 mg/liter or less as formulated.

(B) *Hazard to Wildlife.* (*1*) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels equal to or greater than the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(*2*) Occurs as a residue immediately following application in or on avian feed of an avian species, representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels equal to or greater than the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(*3*) Results in a maximum calculated concentration following direct application to a 6-inch layer of water more than ½ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured on test animals specified in the Registration Guidelines.

(ii) *Chronic Toxicity.* (A) Induces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure; or induces mutagenic effects, as determined by multitest evidence.

(B) Produces any other chronic or delayed toxic effect in test animals at any dosage up to a level, as determined by the Administrator, which is substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety; or

(C) Can reasonably be anticipated to result in significant local, regional, or national population reductions in nontarget organisms, or fatality to members of endangered species.

(iii) *Lack of Emergency Treatments.* Has no known antidotal, palliative, or first aid treatments for amelioration of toxic effects in man resulting from a single exposure.

(4) *Burden of Proof.* Upon finding in accordance with paragraph (1) of this § 162.11(a) that notice pursuant to sections 3(c)(6) or 6(b)(1) of the Act, or notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as ap-

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. USE INDEX

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EPA Index to Pesticide Chemicals

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NABAM*

TYPE PESTICIDE: Fungicide, Algaecide, Antimicrobial, Antifoulant

FORMULATIONS:
FI (13.5%, 1.47 lb/gal or 15%, 17.1%, 2.14-2.21 lb/gal or 22.5%, 2.4-2.5 lb/gal or 25%, 2.88-3.0 lb/gal or 30%)
SC/S (93%)
SC/L (2.0 lb/gal or 22%, 22%)
RTU (0.33 lb/gal or 3.75%, 0.39 lb/gal 4.5%, 0.51 lb/gal or 5.58%, 0.6 lb/gal or 7.5%, 0.9 lb/gal or 9.75%, 1.1 lb/gal or 12%, 1.19 lb/gal or 12.5%, 14%, 1.47 lb/gal or 15%, 1.425 lb/gal or 15%, 18%, 2.1 lb/gal or 22%)

GENERAL WARNINGS AND LIMITATIONS: Protective clothing consisting of long pants, long sleeved shirt, gloves, hat and boots must be worn during mixing and loading for agricultural crop and ornamental plant uses. Wear goggles or face shield, rubber gloves and protective clothing (hats, long sleeve shirt, long pants and boots) when handling for aquatic sites and commercial and industrial uses.
For uses on agricultural crops and ornamentals(with an onion use as the exception), nabam is mixed with zinc sulfate to form zineb. For each 1.0 pound active ingredient or nabam, add 0.75 to 1.0 pound zinc sulfate (36 percent metallic zinc) or 1.0 to 1.25 pounds zinc sulfate (22.8 to 25.5 percent metallic zinc) per 100 gallons of water. Dosages and limits are given in pounds active ingredient nabam. For vegetables, field crops, and ornamentals, unless otherwise specified apply on a regular 7 to 10 day schedule or more frequently under severe disease conditions. Begin when disease first appears and continue as long as disease conditions prevail. Consult a State Agricultural Cooperative Extension Service regarding specific recommendations for these applications, and for fruit spray schedules. Apply with standard high volume, concentrate, or aircraft equipment. A suitable spreader-sticker may be added for certain hard-to-wet crops. Nabam is compatible with most insecticides, fungicides, and nutritional spray mixtures. Do not combine with emulsive or soluble type spray oils as sprayer screens and nozzles may become clogged.
For aquatic sites and commercial and industrial uses, dosages are given in active ingredient nabam.

Definition of Terms:
a.i. - active ingredient
MAI - multiple active ingredient(s)
ppm - parts per million

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*disodium ethylene bisdithiocarbamate

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
/16002AA	Asparagus		N.F.
FJAAPEJ	Rust (Puccinia)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L)	Foliar application. Apply to new fern growth after harvest or to new plantings at first sign of disease. Repeat at 10 day intervals until fern growth is completed.
/28001AA	Beans (lima and snap)		7 ppm as zineb 7 day preharvest interval through 1.0 pound per 100 gallons.
FAAACDP FFABPCN FJAAUAH	Anthracnose (Colletotrichum) Downy mildew (Phytophthora) Rust (Uromyces)	1.0 lb/100 gal or 1.0-1.5 lb/A [100-125 gal/A] (2.0 lb/gal or 22% SC/L)	Foliar application. Apply after first blossoms appear.
/28002AA /13011AA /13021AA /13025AA /28022AA	Beets		7 ppm as zineb, beet (garden) roots only 25 ppm as zineb, beet tops 7 day preharvest interval for beet tops for food or feed through 1.0 pound per 100 gallons.
FFABPAU FMBCCBM	Downy mildew (Peronospora) Leaf spot (Cercospora)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L)	Foliar application.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/13005AA	Broccoli		7 ppm as zineb 7 day preharvest interval through 1.0 pound per 100 gallons.
/13007AA	Cabbage		
/13008AA	Cauliflower		
FFABPAU	Downy mildew (Peronospora)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L) (22% SC/L)	Foliar application. Apply in plant bed and field. For downy mildew, apply at weekly intervals as long as disease is present.
FMBCAAX	Leaf spot (Alternaria)		
	Cabbage		See Broccoli cluster.
/10002AA	Cantaloupe		4 ppm as zineb for cucumbers, melons, and squash 5 day preharvest interval through 1.0 pound per 100 gallons.
/10010AA	Cucumber		
/10012AA	Squash		
/10008AA	Watermelons		
FAAACDP	Anthracnose (Colletotrichum)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L) (22% SC/L)	Foliar application. Apply when vines are 4 to 6 inches long. Repeat at weekly intervals. Direct sprays especially to underside of leaves.
FFABPEA	Downy mildew (Pseudoperonospora)		
FBAQMCO	Gummy stem blight (Mycosphaerella)		
FBATAAX	Leaf blight (Alternaria)		
/28073AA	Carrots		7 ppm as zineb 7 day preharvest interval if tops are to be used as food or feed through 1.0 pound per 100 gallons.
FBASAAX	Alternaria blight (late blight)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L)	Foliar application.
FBAMCBM	Cercospora blight (early blight)		
	Cauliflower		See Broccoli cluster.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28003AA	Celery		5 ppm as zineb 14 day preharvest interval through 1.0 pound per 100 gallons. Remove residues by stripping, trimming, and washing.
FBAMCBM	Early blight (Cercospora)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L) (22% SC/L)	Foliar application. Apply in plant bed and field at weekly intervals.
FBASSBL	Late blight (Septoria)		
/05002AA	Cherry (sour)		7 ppm as zineb 7 day preharvest interval through 0.5 pound per 100 gallons. Mix with 6.0 ounces zinc sulfate (36 percent metallic zinc).
FMBCCDJ	Cherry leaf spot (Coccomyces)	0.5 lb/100 gal (2.0 lb/gal or 22% SC/L)	Delayed dormant, preharvest and postharvest foliar application.
/15005AA	Corn		5 ppm as zineb, sweet corn (kernels plus CWHR) No preharvest interval through 1.0 pound per 100 gallons. Do not feed treated forage to dairy animals or animals being finished for slaughter.
FBATHAM	Helminthosporium leaf spots	1.0 lb/100 gal	Foliar application.
FJAAPEJ	Rust (Puccinia)	1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L)	
	Cucumber		See Cantaloupe cluster.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01014AA	Grapes		7 ppm as zineb 7 day preharvest interval through 1.0 pound per 100 gallons.
FIBFGBG	Black rot (Guignardia)	1.0 lb/100 gal (2.0 lb/gal or 22% SC/L)	Delayed dormant and foliar application.
FFABPCV	Downy mildew (Plasmopara)		
FICAGAP	Ripe rot (Glomerella)		
/08020AA	Hops		60 ppm as zineb 14 day preharvest interval through 1.0 pound per 100 gallons.
FFABPEA	Downy mildew (Pseudoperonospora)	1.0 lb/100 gal (2.0 lb/gal or 22% SC/L)	Delayed dormant and foliar application. Apply drenching spray on crowns when new growth starts. Begin vine sprays at training.
/13011AA	Kale		10 ppm as zineb 10 day preharvest interval through 1.0 pound per 100 gallons.
		Refer to Beets for pest and use information.	
/13020AA	Lettuce		10 ppm as zineb 10 day preharvest interval through 1.0 pound per 100 gallons.
FFABBBA	Downy mildew (Bremia)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L) (22% SC/L)	Soil and foliar application. Apply as a drenching spray in plant bed when seed is planted. Repeat at weekly intervals until transplanting. In field, apply when disease appears. Repeat at weekly intervals or more often under severe disease conditions.
/13021AA	Mustard Greens		10 ppm as zineb 10 day preharvest interval through 1.0 pound per 100 gallons.
		Refer to Beets for pest and use information.	

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/14011AA	Onion		7 ppm as zineb
/16004AA	Onions (green)		7 day preharvest interval for green onions and no preharvest interval for bulb or dry onions through 1.0 pound per 100 gallons.
FKAABAW	Botrytis blight (blast)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L) (22% SC/L)	Foliar application.
FFABPAU	Downy mildew (Peronospora)		
FCAEAAX	Purple blotch (Alternaria)		
/14011DA	Onion		N.F. Apply without zinc sulfate.
FLANUAG	Onion smut (Urocystis)	1.0 lb/A (2.0 lb/gal or 22% SC/L)	At-planting soil application. Apply in sufficient water as a furrow drench at seeding.
/28017AA	Pepper		7 ppm as zineb No preharvest interval through 1.0 pound per 100 gallons.
FAAAQBB	Anthracnose	1.0 lb/100 gal (22% SC/L)	Foliar application.
FMAVCBM	Cercospora leaf spot		
/13024AA	Spinach		10 ppm as zineb 10 day preharvest interval through 1.0 pound per acre.
FFABPAU	Downy mildew (blue mold) (Peronospora)	1.0 lb/100 gal or 1.0-1.5 lb/A (2.0 lb/gal or 22% SC/L) (22% SC/L)	Foliar application.
FGARAAV	White rust (Albugo)		
	Squash		See Cantaloupe cluster.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01016AA	Strawberry		7 ppm as zineb 7 day preharvest interval through 1.0 pound per 100 gallons.
FGAKDBS	Leaf scorch (Diplocarpon)	1.0 lb/100 gal	Delayed dormant and foliar application.
FMBCMCO	Leaf spot (Mycosphaerella)	(2.0 lb/gal or 22% SC/L)	
/13025AA	Swiss Chard		25 ppm as zineb 7 day preharvest interval through 1.0 pound per 100 gallons.
		Refer to Beets for pest and use information.	
/11005AA	Tomato		4 ppm as zineb 5 day preharvest interval through 1.0 pound per 100 gallons.
FAAAGAP	Anthracnose (Glomerella)	1.0 lb/100 gal	Foliar application. Begin when first fruits are set, at first signs of disease, or when plants are set in the field where blights are normally severe.
FHAGCCV	Cladosporium leaf mold	or 1.0-1.5 lb/A	
FBAMAAX	Early blight (Alternaria)	(2.0 lb/gal or 22% SC/L)	
FBASPCN	Late blight (Phytophthora)	(22% SC/L)	
FMBCSBL	Leaf spot (Septoria)		
FMBCSDG	Leaf spot (Stemphylium)		
/28022AA	Turnips		7 ppm as zineb, with or without tops, or turnip greens 7 day preharvest interval for turnip tops for food or feed through 1.0 pound per 100 gallons.
		Refer to Beets for pest and use information.	
	Watermelons		See Cantaloupe cluster.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL NON-FOOD CROP		
	(Ornamental Plants and Forest Trees)		
/34022AA	Azalea		
/34036AA	Camellia		
FBADOAV	Petal blight (Ovulinia) (on azalea)	0.5 lb/100 gal (2.0 lb/gal or 22% SC/L)	Foliar and soil application. Mix with 6.0 ounces zinc sulfate (36 percent metallic zinc). Apply 2 to 3 times per week while flowers are opening. Spray flowers, soil, and litter under the plants.
FBADSAQ	Petal blight (Sclerotinia) (on camellia)		
		1.0 lb/100 gal (22% SC/L)	Foliar and soil application. Apply when flower buds swell in spring. Apply to open flowers, soil, and litter under the plants. Repeat at 3 to 5 day intervals until end of blossoming season.
/31057AA	Carnation		
/31065AA	Chrysanthemum		
/31184AA	Snapdragon		
FAAACDP	Anthracnose (Colletotrichum)	1.0 lb/100 gal (2.0 lb/gal or 22% SC/L)	Foliar application.
FMBCQBB	Leaf spots		
FJAAQBB	Rusts		
/31111AA	Gladiolus		
FMCDBAW	Leaf and flower spot (Botrytis)	1.0 lb/100 gal or (2.0 lb/gal or 22% SC/L)	Foliar application.
FMCDCFH	Leaf and flower spot (Curvularia)		
FMCESDB	Leaf and flower spot (red spot) (Stemphylium)		
		1.0 lb/100 gal [60 gal/A] (22% SC/L)	Foliar application. Apply when disease first appears. Repeat at 3 to 5 day intervals until end of blossoming season.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	AQUATIC NON-FOOD		
	(Aquatic Sites)		
/65018MA	Air Washer Water Systems		In treating air washer systems pre-clean by introducing a suitable detergent solution into the system and allow air washer to run with fan off for 2 hours. Flush. Check all nozzles, and manually clean those that are plugged. May be fed directly from drum or diluted with water and fed by any suitable system. Apply directly to the sump or basin or at any point in the system where formulation will be uniformly mixed.
DBABAAA FYAFQBB	Slime-forming bacteria Slime-forming fungi	0.4-2.4 oz/ 1,000 gal system water (0.39 lb/gal or 4.5% RTU) (1.47 lb/gal or 15% RTU) (18% RTU)	Water treatment (3.0 to 18 ppm active ingredient). Initial dose: Apply 2.4 ounces (18 ppm) 1 to 3 times per week or as needed to control growth. Subsequent dose: When control is evident, apply 0.4 to 0.8 ounce (3.0 to 6.0 ppm) every 3 days or as needed. Formulated with sodium dimethyldithiocarbamate.
		0.4-4.0 oz/ 1,000 gal system water (1.47 lb/gal or 15% RTU)	Water treatment (3.0 to 30 ppm a.i.). Initial dose: Apply 2.4 to 4.0 ounces (18 to 30 ppm) 1 to 3 times per week or as needed to control growth. Subsequent dose: When control is evident, apply 0.4 to 0.8 ounce (3.0 to 6.0 ppm) every 3 days or as needed. Formulated with sodium dimethyldithiocarbamate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65005MA	Brewery Pasteurizers		
DBABAAA	Slime-forming bacteria	0.24-4.8 oz/ 1,000 gal system water (1.47 lb/gal or 15% RTU)	Water treatment (1.8 to 36 ppm active ingredient). Slug or intermittent method. Initial dose: When system is noticeably fouled, apply 0.36 to 4.8 ounces (2.7 to 36 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.36 to 2.4 ounces (2.7 to 18 ppm) every 3 days or as needed to maintain control. Continuous method. Initial dose: When system is noticeably fouled, apply 0.36 to 3.12 ounces (2.7 to 23 ppm). Subsequent dose: Use continuous feed at 0.24 to 1.2 ounces (1.8 to 9.0 ppm). Formulated with sodium dimethyldithiocarbamate.
/65019MA	Commercial and Industrial Water Cooling Towers		Dosage will depend on the condition of the system prior to treatment. Systems which are heavily contaminated should be cleaned first. Apply to the cleaned system or when growth is first noticed. May be fed directly from drum or diluted with water and fed by any suitable system. Apply directly to the sump or basin or at any point in the system where formulation will be uniformly mixed.
DBABAAA FYAFQBB	Slime-forming bacteria Slime-forming fungi	0.4-2.4 oz/ 1,000 gal system water (0.33 lb/gal or 3.75% RTU) (0.39 lb/gal or 4.5% RTU) (0.9 lb/gal or 9.75% RTU) (1.47 lb/gal or 15% RTU) (18% RTU)	Water treatment (3.0 to 18 ppm active ingredient). Initial dose: Apply 2.4 ounces (18 ppm) 1 to 3 times per week or as needed to control growth. Subsequent dose: When control is evident, apply 0.4 to 0.8 ounce (3.0 to 6.0 ppm) every 3 days or as needed. Formulated with sodium dimethyldithiocarbamate.

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Commercial and Industrial Water Cooling Towers (continued)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
		0.4-8.0 oz/ 1,000 gal system water (1.47 lb/gal or 15% RTU)	Water treatment (3.0 to 60 ppm active ingredient). Initial dose: Apply 2.4 to 8.0 ounces (18 to 60 ppm) 1 to 3 times per week or as needed to control growth. Subsequent dose: When control is evident, apply 0.4 to 0.8 ounces (3.0 to 6.0 ppm) every 3 days or as needed. Formulated with sodium dimethyldithiocarbamate.
		1.22 oz/1,000 gal system water (0.51 lb/gal or 5.58% RTU)	Water treatment (9.2 ppm active ingredient). Apply on a continuous basis to system and to make-up water. As a preventive, apply weekly. Formulated with sodium dimethyldithiocarbamate, isopropanol, and 2,4,5-trichlorophenol, potassium salt.
PKAAAAA DBABAAA FYAFQBB	Algae Slime-forming bacteria Slime-forming fungi	52.5-210 lb/ 1,000,000 gal system water or 19.08 oz/ 1,000 gal system water (2.1 lb/gal or 22% RTU)	Water treatment. Initial dose: In a large, clean system, apply 105 pounds per 1,000,000 gallons (13 ppm active ingredient). When system is noticeably fouled, apply 210 pounds (25 ppm). In smaller systems, apply 19.08 ounces (31 ppm), and repeat if needed. Subsequent dose: When control is evident, apply 52.5 to 105 pounds per 1,000,000 gallons (6.3 to 13 ppm) once per week. In smaller systems, apply 19.08 ounces (31 ppm) once per week, and repeat as needed.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Commercial and Industrial Water Cooling Towers (continued)		
/65019MA	(evaporative condensers, heat exchanger water systems, commercial and industrial cooling towers, influent systems such as flow through filters and lagoons, and industrial water scrubbing systems)		
PKAAAAA	Algae	0.24 to 4.8 oz/1,000 gal water system (1.47 lb/gal or 15% RTU)	Water treatment (1.8 to 36 ppm a.i.). Slug or intermittent method. Initial dose: When system is noticeably fouled, apply 0.36 to 4.8 ounces (2.7 to 36 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.36 to 2.4 ounces (2.7 to 18 ppm) every 3 days (daily, for algae) or as needed to maintain control. Continuous method. Initial dose: When system is noticeably fouled, apply 0.36 to 3.12 ounces (2.7 to 23 ppm). For algae, repeat until control is achieved. Subsequent dose: Use continuous feed at 0.24 to 1.2 ounces (1.8 to 9.0 ppm). Formulated with sodium dimethyldithiocarbamate.
OBABAAA	Slime-forming bacteria		
FYAFQBB	Slime-forming fungi		
/65025MA	Oil Recovery Water		Do not apply in marine and/or estuarine oil fields.
FYAFQBB	Fungal slime	1.53-2.85 lb/100 bbl water or 0.15-0.22 lb/100 bbl water (0.39 lb/gal or 4.5% RTU) (1.19 lb/gal or 12.5% RTU) (1.47 lb/gal or 15% RTU) (18% RTU)	Water treatment (3.2 to 62 ppm active ingredient). Apply in secondary and tertiary petroleum waterflood systems. For control of fungi and bacteria, and growth inhibition of *Bacillus cerus* and *Desulfovibrio desulfuricans*, apply 0.15 to 0.22 pound (3.2 to 4.8 ppm). For growth inhibition of heterotrophic bacteria including *Pseudomonas* spp., apply 1.53 to 2.85 pounds (33 to 62 ppm). Inject directly into and mix thoroughly with the produced water, fresh or salt water or commingled water. Formulated with sodium dimethyldithiocarbamate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Oil Recovery Water (continued)		
		1.2-75 ppm a.i. (1.1 lb/gal or 12% RTU) (1.47 lb/gal or 15% RTU)	Water treatment. Apply to underground flood water. Formulated with sodium dimethyldithiocarbamate; or ethylenediamine and sodium dimethyldithiocarbamate.
DBABAAA	Slime-forming bacteria	0.25-1.22 lb/ 1,000 gal total volume (1.47 lb/gal or 15% RTU)	Water treatment (30 to 146 ppm a.i.). Slug or intermittent method. Initial dose: Apply 1.22 pounds (146 ppm). Subsequent dose: Apply 0.25 pound (30 ppm) weekly to maintain control. Formulated with sodium dimethyldithiocarbamate.
/65008MA	Pulp and Paper Mill Systems		Apply depending upon the type of stock, complexity of the system, quality of raw water, and type and degree of contamination. May be drip fed continuously from the drum or fed by suitable chemical pumps such as adjustable proportioning types; variable speed, positive displacement type; or by the reciprocating type. The formulation should be fed as early as possible in the system at such points including the hydropulper, machine chest or broke system. May be used as a slimicide in the manufacture of paper and paperboard that contact food in accordance with prescribed conditions (CFR 21, Indirect Food Additives, Section 176.300).
DBABAAA FYAFQBB	Slime-forming bacteria Slime-forming fungi	0.015-0.3 lb/ ST finished paper (0.39 lb/gal or 4.5% RTU) (1.47 lb/gal or 15% RTU) (18% RTU)	Water treatment. Continuous treatment is recommended, but slug or intermittent is also suggested on certain labeling. Formulated with sodium dimethyldithiocarbamate.

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Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
Pulp and Paper Mill Systems (continued)		
	0.088-0.44 lb/ST pulp or paper produced (dry basis) (2.1 lb/gal or 22% RTU)	Water treatment. For slime control in white water apply using either continous feed or semi-slug addition. Average starting dose is 0.11 pound.
	0.068-0.34 lb/ST of pulp or paper (dry basis) (1.47 lb/gal or 15% RTU)	Water treatment. Intermittent method. Apply 0.2 to 0.34 pound for 2 hours every 8 hours. Continuous method. Apply 0.068 to 0.23 pound on a continuous basis. Formulated with sodium dimethyldithiocarbamate.
	0.023-0.38 lb/ST pulp or paper produced (1.47 lb/gal or 15% RTU)	Water treatment. Slug method. Initial dose: When the system is noticeably fouled, apply 0.023 to 0.38 pound. Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.023 to 0.3 pound. Treat as needed to maintain control. Continuous method. Initial dose: Apply as in slug method. Subsequent dose: Maintain control by continuous feeding at the levels in slug method. Formulated with sodium dimethyldithiocarbamate.
	0.11-0.33 lb/ST dry pulp (2.1 lb/gal or 22% RTU)	Water treatment. Apply by slug method to troubled areas. Intermittent or continuous feeding to the white water, the beaters, hydropulpers, etc., can also be used.
	0.028-0.28 lb/ST pulp or paper produced (14% RTU)	Water treatment. Apply directly to mill system. Formulated with sodium dimethyldithiocarbamate and sodium pentachlorophenate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Pulp and Paper Mill Systems (continued)		
		0.06-0.24 lb/ ST dry paper or paperboard products (1.1 lb/gal or 12% RTU)	Water treatment. Formulated with ethylenediamine and sodium dimethyldithiocarbamate.
		0.038 lb/ST finished paper (0.6 lb/gal or 7.5% RTU)	Water treatment. Apply at beater, fan pump, head box, or wire tray by continuous or slug feed, depending on system. Formulated with alkenyl (90% C18, 10% C16) dimethyl ethyl ammonium bromide.
/65028MA	Seawater Heat Exchangers (shipboard)		Apply to clean systems. Feed directly from the drum. The preferred feed point is immediately after the strainer. Do not feed to a system while the cooling water is used as either a brine source or a heat supply for fresh water evaporators.
IIDAAAC DBABAAA FYAFQBB	Barnacle larvae Slime-forming bacteria Slime-forming fungi	1.5 ppm a.i. (1.47 lb/gal or 15% RTU)	Water treatment. Apply 1.5 ppm active ingredient for 100 minutes every 3 to 4 days. This is accomplished by feeding 1.5 liters formulation over a 100 minute period for every 100 tons per hour of flow rate. Formulated with sodium dimethyldithiocarbamate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65005MA	Sugar Beet Processing Water		The formulation should be fed directly into the process. The point or points of addition will depend on mill design. Frequently, the dosage will be split between the fresh water entering the diffuser, into the pressed pulp water return line to the diffuser or fed directly into a certain point in the diffuser depending on diffuser type. Feed through a chemical feed pump such as the adjustable proportioning type; the variable feed, positive displacement type; or the reciprocating type. May be used to control microorganisms in sugar beet mills in accordance with prescribed conditions at a level of 3.0 ppm active ingredient by weight of raw beets (CFR 21, Secondary Direct Food Additives, Section 173.320). Therefore, do not exceed a feed rate of 5.88 pounds active ingredient per 1,000 short tons of beets sliced per 24 hours.
DBABAAA	Slime-forming bacteria	1.5-3.0 ppm a.i. by weight of beets sliced per day (1.47 lb/gal or 15% RTU)	Processing water treatment. Feed continuously. In general, 1.5 ppm will provide adequate control, however, the rate may be increased to 3.0 ppm when slicing beets deteriorated by freezing or lengthy storage. The 1.5 to 3.0 ppm levels can be achieved by adding 0.034 to 0.069 ounce active ingredient per minute per 1,000 short tons of beets sliced per day. Refer to labeling for chart on dosages for varying amounts of beets sliced per day. Formulated with sodium dimethyldithiocarbamate.
FYAFQBB	Slime-forming fungi		

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65005MA	Sugar Beet Flume Water Transporting and Washing Systems		
DBABAAA FZZZQBB	Bacteria Fungi	0.3-0.77 ppm a.i. or 2.57-6.48 lb/1,000,000 gal in system (0.39 lb/gal or 4.5% RTU) (1.47 lb/gal or 15% RTU) (18% RTU)	Water treatment. Apply initially at high rate on a continuous or once per shift basis. Thereafter, add at low rate to the system per 8 hour shift. The concentration may be increased to high rate per shift if a decrease in pH or increase in odor is detected. Formulated with sodium dimethyldithiocarbamate.
/650050A	Sugarcane Processing		The formulation should be fed directly into the cane juice so that the treated juice circulates to all parts of the mill tandem. The point or points of addition will depend on mill design. Frequently, the dosage will be split between the crusher juice and juice from the last mill. The best addition is to the juice which is circulated back to the crusher or first mill. Do not add to maceration water. Feed through a chemical feed pump such as the adjustable proportioning type; the variable feed, positive displacement type; or the reciprocating type. May be used to control microorganisms in sugarcane mills in accordance with prescribed conditions at a level of 3.0 ppm active ingredient by weight of raw cane (CFR 21, Secondary Direct Food Additives, Section 173.320). Therefore, do not exceed a feed rate of 5.88 pounds active ingredient per 1,000 short tons of cane ground per 24 hours.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Sugarcane Processing (continued)		
FZZZQBB	Fungi	1.5-3.0 ppm a.i. by weight of cane ground per day (0.33 lb/gal or 3.75% RTU) (0.39 lb/gal or 4.5% RTU) (1.47 lb/gal or 15% RTU) (18% RTU)	Sugarcane juice treatment. The standard dose is 1.5 ppm. Conditions warranting some increase would be grinding of cane damaged through freezing, poor weather, or delays between cutting and grinding. The 1.5 to 3.0 ppm levels can be achieved by adding 0.034 to 0.069 ounce active ingredient per minute per 1,000 short tons of cane ground per day. Refer to labeling for chart on dosages for varying amounts of cane ground per day. Formulated with sodium dimethyldithiocarbamate.
	INDOOR		
	(Industrial Preservatives and Additives)		
/810040A	Fuel Oil (No. 2 oil, intermediate fuel oil, and No. 6 oil), Lubricating Oil, and Hydraulic Fluids (storage)		
FYAAQAA FYAAQBB	Bacteria Fungi	0.78 lb/ST contaminated fluid or 45 ppm a.i. by weight (1.47 lb/gal or 15% RTU)	Additive incorporation. Apply initially at specified rate. Subsequent dosages may be decreased once the contaminants have been brought under control. Formulated with sodium dimethyldithiocarbamate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/810050A	**Leather**		
	(brining and curing hides)		
FYADQBB FYADQBB	Bacteria Fungi	0.46-0.064 lb/100 hides processed (1.47 lb/gal or 15% RTU)	Preservative incorporation. Aids in the preservation of stored hides when added to the raceway. Formulated with sodium dimethyldithiocarbamate.
	(fat liquoring stock)		
FYABQBB	Mold	0.075-0.15 lb/1,000 lb wet weight (1.47 lb/gal or 15% RTU)	Preservative incorporation. Protects stock from mold damage due to the presence of extracts, fillers, and oils. Formulated with sodium dimethyldithiocarbamate.
	(tanning)		
YABQBB	Mold	0.09-0.15 lb/1,000 lb white weight (1.47 lb/gal or 15% RTU)	Preservative incorporation. Rate depends upon the climate and length of holding time. Add prior to the last bicarbonate addition. Formulated with sodium dimethyldithiocarbamate.
810060A	**Leather Processing Liquors**		
	(pickling liquor)		
YABQBB	Mold	0.075-0.15% a.i. (1.47 lb/gal or 15% RTU)	Preservative incorporation. Prevents mold damage of pickled stock for 3 weeks. Add prior to the addition of sulfuric acid. Formulated with sodium dimethyldithiocarbamate.
	(soaking liquors)		
ADQBB	Fungi	0.09-0.15 lb/ ST solution (1.47 lb/gal or 15% RTU)	Preservative incorporation. To prevent loss of hide substance due to fungal action in soaking liquors, apply at low rate. If hides are to be held longer than 2 weeks, apply the high rate. Formulated with sodium dimethyldithiocarbamate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/810070A	Metalworking Cutting Fluids		
FYAIQBB	Fungi	0.012-0.075% a.i. (1.1 lb/gal or 12% RTU) (1.47 lb/gal or 15% RTU)	Preservative incorporation. For use in cutting fluids and other metalworking fluids. Formulated with sodium dimethyldithiocarbamate; or ethylenediamine and sodium dimethyldithiocarbamate.
		0.41-0.1 lb/100 gal coolant (2.1 lb/gal or 22% RTU)	Preservative incorporation (49 to 123 ppm active ingredient). For use in water-dispersible metalworking coolants. Dosage depends upon the severity of the problem. For individual machines, add directly to the sump; for central systems, add to the discharge side of the reservoir. Repeat weekly. When dosage level exceeds 74 ppm, it is recommended that multiple additions of 25 ppm each be made at hourly intervals.
'810080A	Oil Recovery Drilling Fluids		Do not apply in marine and/or estuarine oil fields.
)BADAAA	Deterioration/spoilage bacteria	1.425-7.35 lb/100 bbl mud (0.39 lb/gal or 4.5% RTU) (1.19 lb/gal or 12.5% RTU) (1.47 lb/gal or 15% RTU) (18% RTU)	Additive incorporation. Use in water-based drilling muds such as those containing starches, xanthanate gums, and wood sugars. May be put through the mud hopper or added to the sump suction. Formulated with sodium dimethyldithiocarbamate.
'YADQBB	Fungi		
)BABAAA	Slime-forming bacteria		
		8.58 lb/100 bbl (1.47 lb/gal or 15% RTU)	Additive incorporation. Formulated with sodium dimethyldithiocarbamate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Oil Recovery Drilling Fluids (continued)		
		0.0006-0.15% a.i. by weight/bbl mud or packer fluid (1.1 lb/gal or 12% RTU) (1.47 lb/gal or 15% RTU)	Additive incorporation. Use in drilling muds, gypsum muds, and packer fluids. Formulated with sodium dimethyldithiocarbamate; or ethylenediamine and sodium dimethyldithiocarbamate.
	(workover and completion fluids)		
DBADAAA	Deterioration/ spoilage bacteria	0.37-1.47 lb/ 1,000 gal fluids (1.47 lb/gal or 15% RTU)	Additive incorporation. Apply to water based workover or completion fluids. Formulated with sodium dimethyldithiocarbamate.
FYADQBB	Fungi		
DBABAAA	Slime-forming bacteria		
DBADAAA	Deterioration/ spoilage bacteria	8.58 lb/100 bbl (1.47 lb/gal or 15% RTU)	Additive incorporation. Formulated with sodium dimethyldithiocarbamate.
DBABAAA	Slime-forming bacteria		
/810010A /810140A /810120A /810160A /810090A /810020A	Preservation of Adhesives and Animal Glues, Inks, Latex, Mineral Slurries, Paints and Coatings and Paper Coatings		
FYADQBB	Fungi	0.006-0.15% a.i. (1.1 lb/gal or 12% RTU) (1.47 lb/gal or 15% RTU)	Preservative incorporation. Formulated with sodium dimethyldithiocarbamate; or ethylenediamine and sodium dimethyldithiocarbamate.
/810190A	Preservation of Applied Films (paints and other coatings, adhesives and animal glues)		
FYABQBB	Mildew	0.012-0.15% a.i. (1.1 lb/gal or 12% RTU) (1.47 lb/gal or 15% RTU)	Preservative incorporation. Formulated with sodium dimethyldithiocarbamate; or ethylenediamine and sodium dimethyldithiocarbamate.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/810160A	Preservation in Pulp and Paper Mills		
FYADQBB	Fungi	30-150 ppm a.i. (1.47 lb/gal or 15% RTU)	Preservative incorporation. Add directly to the material to be preserved prior to manufacturing into the finished product, i.e., pulp, broke, polymers, defoamers, alum, emulsions, adhesives, paper mill coatings, pigment slurries, etc. The dosage rate will depend upon the material to be preserved and the storage time. The usual addition should be 30 to 45 ppm. Under extreme conditions of spoilage, the dosage rate should be increased to 38 to 120 ppm. The above recommendations are based on a maximum storage time of 2 weeks. For storage greater than 2 weeks, the maximum concentration should be increased to 150 ppm. Formulated with sodium dimethyldithiocarbamate.
		0.088-0.44 lb/ST pulp (dry basis) (2.1 lb/gal or 22% RTU)	Pulp preservation.
		0.03-0.38 lb/ 1,000 gal (1.47 lb/gal or 15% RTU)	Additives system treatment (3.6 to 45 ppm active ingredient). Slug method. Initial dose: Applications should be made directly at the rate of 0.03 to 0.38 pound per 1,000 gallons (3.6 to 45 ppm). Repeat until control is achieved. Subsequent dose: Apply 0.03 to 0.3 pound per 1,000 gallons (3.6 to 36 ppm). Continuous method. Initial dose: Apply as in slug method. Subsequent dose: Apply by continuous feeding at the levels in the slug method.

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Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

AERIAL AND TANK MIX APPLICATIONS

01500
AAAAA
Aerial Application

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Refer to
TERRESTRIAL FOOD CROPS
All sites
TERRESTRIAL NON-FOOD CROPS
All sites

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Listing of Registered Pesticide Products by Formulation

13.5002 13.5% formulation intermediate
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
000400-00121 031910-00010

15.0002 15% (1.47 lb/gal) formulation intermediate
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
000400-00119 031910-00001

17.1002 17.1% formulation intermediate
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
000400-00123

22.5002 22.5% (2.14-2.21 lb/gal) formulation intermediate
nabam (014503)
031910-00008

5.0002 25% (2.4-2.5 lb/gal) formulation intermediate
nabam (014503)
031910-00009

0.0002 30% (2.88-3.0 lb/gal) formulation intermediate
nabam (014503)
000400-00122 031910-00007*
*jacket currently unavailable for review

3.0015 93% soluble concentrate/solid
nabam (014503)
000707-00070*
*suspended 3-84

2.0015 22% (2.0 lb/gal) soluble concentrate/liquid
nabam (014503)
000707-00003

2.0015 22% soluble concentrate/liquid
nabam (014503)
000279-00827

3.7516 3.75% (0.33 lb/gal) liquid-ready to use
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
033576-00037

4.5016 4.5% (0.39 lb/gal) liquid-ready to use
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
009386-00023 031910-00011

5.5816 5.58% (0.51 lb/gal) liquid-ready to use
nabam (014503), sodium dimethyldithiocarbamate (034804), isopropanol (047501) plus 2,4,5-trichlorophenol, potassium salt (064204)
003635-00110

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Listing of Registered Pesticide Products by Formulation (continued)

&007.5016 7.5% (0.6 lb/gal) liquid-ready to use
nabam (014503) plus alkenyl (90% C18, 10% C16) dimethyl ethyl ammonium bromide (069102)
008103-00002

&009.7516 9.75% (0.9 lb/gal) liquid-ready to use
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
010485-00016

&012.0016 12% (1.1 lb/gal) liquid-ready to use
nabam (014503), ethylenediamine (004205) plus sodium dimethyldithiocarbamate (034804)
001757-00061

&012.5016 12.5% (1.19 lb/gal) liquid-ready to use
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
031910-00016 031910-00018

&014.0016 14% liquid-ready to use
nabam (014503), sodium dimethyldithiocarbamate (034804) plus sodium pentachlorophenate (063003)
003876-00060

&015.0016 15% (1.47 lb/gal) liquid-ready to use
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
000337-00058 001706-00164 001757-00048 001757-00051
001757-00059 001757-00069 003876-00062 004643-00028
005009-00022 005009-00023 008540-00017 008591-00028
009386-00007 009386-00011 009640-00031 010349-00029
010349-00030 011576-00013 022555-00008 031910-00002
033561-00001 033576-00031 033576-00036 033772-00001
034571-00003 035909-00001 045017-00014

&015.0016 15% (1.425 lb/gal) liquid-ready to use
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
031910-00019

&018.0016 18% liquid-ready to use
nabam (014503) plus sodium dimethyldithiocarbamate (034804)
031910-00012

&022.0016 22% (2.1 lb/gal) liquid-ready to use
nabam (014503)
001677-00032 007779-00009 007779-00018 007779-00019
010329-00001

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Listing of Registered Pesticide Products by Formulation (continued)

9999999 State Label Registration

CA Reg. No.
001202-05100

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Listing by Site/Pest and Site/Formulation/Registration Number

TERRESTRIAL FOOD CROP

(Agricultural Crops)

/16002AA	Asparagus
FJAAPEJ	Rust (Puccinia)
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/28001AA	Beans (lima and snap)
FAAACDP	Anthracnose (Colletotrichum)
FFABPCN	Downy mildew (Phytophthora)
FJAAUAH	Rust (Uromyces)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/28002AA	Beets
FFABPAU	Downy mildew (Peronospora)
FMBCCBM	Leaf spot (Cercospora)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/13005AA	Broccoli
FFABPAU	Downy mildew (Peronospora)
FMBCAAX	Leaf spot (Alternaria)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/13007AA	Cabbage
FFABPAU	Downy mildew (Peronospora)
FMBCAAX	Leaf spot (Alternaria)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003

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Listing by Site/Pest and Site/Formulation/Registration Number (continued)

	Cabbage (continued)
	(22% SC/L)
	000279-00827
/10002AA	**Cantaloupe**
FAAACDP	Anthracnose (Colletotrichum)
FFABPEA	Downy mildew (Pseudoperonospora)
FBAQMCO	Gummy stem blight (Mycosphaerella)
FBATAAX	Leaf blight (Alternaria)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/28073AA	**Carrots**
FBASAAX	Alternaria blight (late blight)
FBAMCBM	Cercospora blight (early blight)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/13008AA	**Cauliflower**
FFABPAU	Downy mildew (Peronospora)
FMBCAAX	Leaf spot (Alternaria)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/28003AA	**Celery**
FBAMCBM	Early blight (Cercospora)
FBASSBL	Late blight (Septoria)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003

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Listing by Site/Pest and Site/Formulation/Registration Number (continued)

	Celery (continued)
	(22% SC/L)
	000279-00827
/05002AA	Cherry (sour)
FMBCCDJ	Cherry leaf spot (Coccomyces)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/02000AA	Citrus Fruits
FMAYMCO	Greasy spot (Mycosphaerella)
ILAAADA	Rust mites
	(93% SC/S)
	000707-00070
/15005AA	Corn
FBATHAM	Helminthosporium leaf spots
FJAAPEJ	Rust (Puccinia)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/10010AA	Cucumber
FAAACDP	Anthracnose (Colletotrichum)
FFABPEA	Downy mildew (Pseudoperonospora)
FBAQMCO	Gummy stem blight (Mycosphaerella)
FBATAAX	Leaf blight (Alternaria)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/01014AA	Grapes
FIBFGBG	Black rot (Guignardia)
FFABPCV	Downy mildew (Plasmopara)
FICAGAP	Ripe rot (Glomerella)
	(93% SC/S)
	000707-00070

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Appendix B

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

Grapes (continued)

(2.0 lb/gal or 22% SC/L)
000707-00003

/08020AA Hops
FFABPEA Downy mildew (Pseudoperonospora)
(2.0 lb/gal or 22% SC/L)
000707-00003

/13011AA Kale
FFABPAU Downy mildew (Peronospora)
FMBCCBM Leaf spot (Cercospora)
(93% SC/S)
000707-00070

(2.0 lb/gal or 22% SC/L)
000707-00003

/13020AA Lettuce
FFABBBA Downy mildew (Bremia)
(93% SC/S)
000707-00070

(2.0 lb/gal or 22% SC/L)
000707-00003

(22% SC/L)
000279-00827

/13021AA Mustard Greens
FFABPAU Downy mildew (Peronospora)
FMBCCBM Leaf spot (Cercospora)
(93% SC/S)
000707-00070

(2.0 lb/gal or 22% SC/L)
000707-00003

/14011AA Onion
FKAABAW Botrytis blight (blast)
FFABPAU Downy mildew (Peronospora)
FCAEAAX Purple blotch (Alternaria)
(93% SC/S)
000707-00070

(2.0 lb/gal or 22% SC/L)
000707-00003

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Listing by Site/Pest and Site/Formulation/Registration Number (continued)

	Onion (continued)
	(22% SC/L)
	000279-00827
/14011DA	Onion
FLANUAG	Onion smut (Urocystis)
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/16004AA	Onions (green)
FKAABAW	Botrytis blight (blast)
FFABPAU	Downy mildew (Peronospora)
FCAEAAX	Purple blotch (Alternaria)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/28017AA	Pepper
FAAAQBB	Anthracnose
FMAVCBM	Cercospora leaf spot
	(22% SC/L)
	000279-00827
/13024AA	Spinach
FFABPAU	Downy mildew (blue mold) (Peronospora)
FGARAAV	White rust (Albugo)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/10012AA	Squash
FAAACDP	Anthracnose (Colletotrichum)
FFABPEA	Downy mildew (Pseudoperonospora)
FBAQMCO	Gummy stem blight (Mycosphaerella)
FBATAAX	Leaf blight (Alternaria)
	(93% SC/S)
	000707-00070

DRAFT

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

	Squash (continued)
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/01016AA	Strawberry
FGAKDBS	Leaf scorch (Diplocarpon)
FMBCMCO	Leaf spot (Mycosphaerella)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/13025AA	Swiss Chard
FFABPAU	Downy mildew (Peronospora)
FMBCCBM	Leaf spot (Cercospora)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
/11005AA	Tomato
FAAAGAP	Anthracnose (Glomerella)
FHAGCCV	Cladosporium leaf mold
FBAMAAX	Early blight (Alternaria)
FBASPCN	Late blight (Phytophthora)
FMBCSBL	Leaf spot (Septoria)
FMBCSDG	Leaf spot (Stemphylium)
	(93% SC/S)
	000707-00070
	(2.0 lb/gal or 22% SC/L)
	000707-00003
	(22% SC/L)
	000279-00827
/28022AA	Turnips
FFABPAU	Downy mildew (Peronospora)
FMBCCBM	Leaf spot (Cercospora)
	(93% SC/S)
	000707-00070

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EPA Index to Pesticide Chemicals

NABAM

Appendix B

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

	Turnips (continued)
	(2.0 lb/gal or 22% SC/L) 000707-00003
/10008AA	Watermelons
FAAACDP	Anthracnose (Colletotrichum)
FFABPEA	Downy mildew (Pseudoperonospora)
FBAQMCO	Gummy stem blight (Mycosphaerella)
FBATAAX	Leaf blight (Alternaria)
	(93% SC/S) 000707-00070
	(2.0 lb/gal or 22% SC/L) 000707-00003
	(22% SC/L) 000279-00827
/28065AA	Wheat
FJAGPEJ	Leaf rust (Puccinia)
FJAMPEJ	Stem rust (Puccinia)
	(93% SC/S) 000707-00070
	TERRESTRIAL NON-FOOD CROP
	(Ornamental Plants and Forest Trees)
/34022AA	Azalea
FBADOAV	Petal blight (Ovulinia) (on azalea)
FBADSAQ	Petal blight (Sclerotinia) (on camellia)
	(93% SC/S) 000707-00070
	(2.0 lb/gal or 22% SC/L) 000707-00003
	(22% SC/L) 000279-00827
/34036AA	Camellia
FBADOAV	Petal blight (Ovulinia) (on azalea)
FBADSAQ	Petal blight (Sclerotinia) (on camellia)
	(93% SC/S) 000707-00070

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Listing by Site/Pest and Site/Formulation/Registration Number (continued)

Camellia (continued)

(2.0 lb/gal or 22% SC/L)
000707-00003

(22% SC/L)
000279-00827

/31057AA Carnation
FAAACDP Anthracnose (Colletotrichum)
FMBCQBB Leaf spots
FJAAQBB Rusts
(93% SC/S)
000707-00070

(2.0 lb/gal or 22% SC/L)
000707-00003

/31065AA Chrysanthemum
FAAACDP Anthracnose (Colletotrichum)
FMBCQBB Leaf spots
FJAAQBB Rusts
(93% SC/S)
000707-00070

(2.0 lb/gal or 22% SC/L)
000707-00003

/31111AA Gladiolus
FMCDBAW Leaf and flower spot (Botrytis)
FMCDCFH Leaf and flower spot (Curvularia)
FMCESDB Leaf and flower spot (red spot) (Stemphylium)
(93% SC/S)
000707-00070

(2.0 lb/gal or 22% SC/L)
000707-00003

(22% SC/L)
000279-00827

/31184AA Snapdragon
FAAACDP Anthracnose (Colletotrichum)
FMBCQBB Leaf spots
FJAAQBB Rusts
(93% SC/S)
000707-00070

Snapdragon (continued)

(2.0 lb/gal or 22% SC/L)
000707-00003

AQUATIC NON-FOOD

(Aquatic Sites)

/65018MA Air Washer Water Systems
DBABAAA Slime-forming bacteria
FYAFQBB Slime-forming fungi
(0.39 lb/gal or 4.5% RTU)
031910-00011

(1.47 lb/gal or 15% RTU)
000337-00058 001757-00051 004643-00028 005009-00022
005009-00023 008591-00028 009386-00011 009640-00031
011576-00013 031910-00002 033576-00036 033772-00001

(18% RTU)
031910-00012

/65005MA Brewery Pasteurizers
DBABAAA Slime-forming bacteria
(1.47 lb/gal or 15% RTU)
003876-00062 034571-00003

/65019MA Commercial and Industrial Water Cooling Towers
PKAAAAA Algae
DBABAAA Slime-forming bacteria
FYAFQBB Slime-forming fungi
(0.33 lb/gal or 3.75% RTU)
033576-00037

(0.39 lb/gal or 4.5% RTU)
009386-00023 031910-00011

(0.51 lb/gal or 5.58% RTU)
003635-00110

(0.9 lb/gal or 9.75% RTU)
010485-00016

(1.47 lb/gal or 15% RTU)
000337-00058 001757-00051 003876-00062 004643-00028
005009-00022 005009-00023 008540-00017 008591-00028
009386-00011 009640-00031 011576-00013 031910-00002

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Listing by Site/Pest and Site/Formulation/Registration Number (continued)

Commercial and Industrial Water Cooling Towers (continued)

(1.47 lb/gal or 15% RTU) (continued)

033561-00001 033576-00036 033772-00001 034571-00003
035909-00001

(18% RTU)
031910-00012

65019MA (evaporative condensers, heat exchanger water systems, commercial and industrial cooling towers, influent systems such as flow through filters and lagoons, and industrial water scrubbing systems)
KAAAAA Algae
BABAAA Slime-forming bacteria
YAFQBB Slime-forming fungi
(1.47 lb/gal or 15% RTU)
000337-00058 001757-00051 003876-00062 004643-00028
005009-00022 005009-00023 008540-00017 008591-00028
009386-00011 009640-00031 011576-00013 031910-00002
033561-00001 033576-00036 033772-00001 034571-00003
035909-00001

65025MA Oil Recovery Water
YAFQBB Fungal slime
BABAAA Slime-forming bacteria
(0.39 lb/gal or 4.5% RTU)
031910-00011

(1.1 lb/gal or 12% RTU)
001757-00061

(1.19 lb/gal or 12.5% RTU)
031910-00016 031910-00018

(1.47 lb/gal or 15% RTU)
001757-00059 009386-00007 010349-00029 022555-00008
031910-00002

(1.425 lb/gal or 15% RTU)
031910-00019

(18% RTU)
031910-00012

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NABAM

Appendix B

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

/65008MA **Pulp and Paper Mill Systems**
DBABAAA Slime-forming bacteria
FYAFQBB Slime-forming fungi
(0.39 lb/gal or 4.5% RTU)
031910-00011

(0.6 lb/gal or 7.5% RTU)
008103-00002

(1.1 lb/gal or 12% RTU)
001757-00061

(14% RTU)
003876-00060

(1.47 lb/gal or 15% RTU)
001757-00059 004643-00028 005009-00022 005009-00023
008591-00028 009386-00007 009386-00011 031910-00002
033576-00031 033772-00001 045017-00014

(18% RTU)
031910-00012

(2.1 lb/gal or 22% RTU)
001677-00032 007779-00009 010329-00001

/65028MA **Seawater Heat Exchangers** (shipboard)
IIDAAAC Barnacle larvae
DBABAAA Slime-forming bacteria
FYAFQBB Slime-forming fungi
(1.47 lb/gal or 15% RTU)
001757-00048

/65005MA **Sugar Beet Processing Water**
DBABAAA Slime-forming bacteria
FYAFQBB Slime-forming fungi
(1.47 lb/gal or 15% RTU)
001706-00164 001757-00059 009386-00011 022555-00008
031910-00002

/65005MA **Sugar Beet Flume Water Transporting and Washing Systems**
DBABAAA Bacteria
FZZZQBB Fungi
(0.39 lb/gal or 4.5% RTU)
031910-00011

(1.47 lb/gal or 15% RTU)
001706-00164 031910-00002

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Listing by Site/Pest and Site/Formulation/Registration Number (continued)

Sugar Beet Flume Water Transporting and Washing Systems (continued)

(18% RTU)
031910-00012

/650050A Sugarcane Processing
FZZZQBB Fungi
(0.33 lb/gal or 4.5% RTU)
033576-00037

(0.39 lb/gal or 4.5% RTU)
009386-00023 031910-00011

(1.47 lb/gal or 15% RTU)
001706-00164 001757-00059 004643-00028 005009-00022
005009-00023 009386-00011 022555-00008 031910-00002
033576-00036 033772-00001

(18% RTU)
031910-00012

INDOOR

(Commercial and Industrial Uses)

/810040A Fuel Oil (No. 2 oil, intermediate fuel oil, and No. 6 oil), Lubricating Oil, and Hydraulic Fluids (storage)
FYAAQAA Bacteria
FYAAQBB Fungi
(1.47 lb/gal or 15% RTU)
031910-00002

/810050A Leather

(brining and curing hides)
FYADQBB Bacteria
FYADQBB Fungi
(1.47 lb/gal or 15% RTU)
001757-00069

(fat liquoring stock)
FYABQBB Mold
(1.47 lb/gal or 15% RTU)
001757-00069

DRAFT

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

	Leather (continued)
	(tanning)
FYABQBB	Mold
	(1.47 lb/gal or 15% RTU)
	001757-00069
/810060A	**Leather Processing Liquors**
	(pickling liquor)
FYABQBB	Mold
	(1.47 lb/gal or 15% RTU)
	001757-00069
	(soaking liquors)
FYADQBB	Fungi
	(1.47 lb/gal or 15% RTU)
	001757-00069
/810070A	**Metalworking Cutting Fluids**
FYAIQBB	Fungi
	(1.1 lb/gal or 12% RTU)
	001757-00061
	(1.47 lb/gal or 15% RTU)
	001757-00059
	(2.1 lb/gal or 22% RTU)
	007779-00018
/810080A	**Oil Recovery Drilling Fluids**
DBADAAA	Deterioration/spoilage bacteria
FYADQBB	Fungi
DBABAAA	Slime-forming bacteria
	(0.39 lb/gal or 4.5% RTU)
	009386-00023 031910-00011
	(1.1 lb/gal or 12% RTU)
	001757-00061
	(1.19 lb/gal or 12.5% RTU)
	031910-00016 031910-00018
	(1.47 lb/gal or 15% RTU)
	001757-00059 009386-00007 010349-00029 010349-00030 022555-00008 031910-00002
	(18% RTU)
	031910-00019

DRAFT

Listing by Site/Pest and Site/Formulation/Registration Number (continued)

Oil Recovery Drilling Fluids (continued)

(workover and completion fluids)
DBADAAA Deterioration/spoilage bacteria
FYADQBB Fungi
DBABAAA Slime-forming bacteria
(1.47 lb/gal or 15% RTU)
009386-00007 022555-00008

/810010A Preservation of Adhesives and Animal Glues, Inks, Latex, Mineral Slurries, Paints and Coatings and Paper Coatings
/810020A
/810090A
/810120A
/810140A
FYADQBB Fungi
(1.1 lb/gal or 12% RTU)
001757-00061

(1.47 lb/gal or 15% RTU)
001757-00059 045017-00014

/810190A Preservation of Applied Films (paints and other coatings, adhesives and animal glues)
FYABQBB Mildew
(1.1 lb/gal or 12% RTU)
001757-00061

(1.47 lb/gal or 15% RTU)
001757-00059 045017-00014

/810160A Preservation in Pulp and Paper Mills
FYADQBB Fungi
(1.47 lb/gal or 15% RTU)
045017-00014

(2.1 lb/gal or 22% RTU)
007779-00009

IV. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Nabam Standard

MRID	CITATION
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00088825	Vonk, J.W. (1975) Chemical Decomposition of Bisdithiocarbamate Fungicides and Their Metabolism by Plants and Microorganisms. (Unpublished study received Dec 9, 1981 under 707-78; prepared by Drukkerij Elinkwijk BV, The Netherlands, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-G)
00088826	Nash, R.G. (1976) Uptake of ethylenebis(dithiocarbamate) fungicides and ethylenethiourea by soybeans. Journal of Agricultural and Food Chemistry 24(3):596-601. (Also in unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-H)
00088831	Rohm and Haas Company (1969) A Study To Determine Residue Levels in Milk and Tissues from a Cow Fed C14 Dithane M-45: Lab 23 Res. Rpt. No. 18. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070528-N)
00088833	Lyman, W.R.; Lacoste, R.J. (1975) New developments in the chemistry and fate of ethylenebisdithiocarbamate fungicides. Pages 67-74 In Environmental Quality and Safety: Supplement Volume III: Pesticides: Lectures held at the IUPAC Third International Congress of Pesticide Chemistry; Jul 3-9, 1974; Helsinki, Finland. Edited by Frederick Coulston; et al. Stuttgart, West Germany: Georg Thieme Publishers. (Also in unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-P)
00088834	Saxton, A.D. (1972) A C14-ethylene Thiourea Rat-feeding Study: An Experiment To Determine the Excretion Pattern and the Accumulation and Decline in Thyroid Tissues of C14 Residues: Research Report No. 23-51. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-Q)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Nabam Standard

MRID	CITATION
00088835	Saxton, A.D. (1972) A C14-Jaffe's Base Rat-feeding Study: An Experiment To Determine the Excretion Pattern and the Accumulation of C14 Residues in the Body Tissues: Research Report No. 23-54. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 070528-R)
00088891	Haines, L.D.; Adler, I.L. (1973) Gas chromatographic determination of ethylene thiourea residues. Journal of the Association of Official Analytical Chemists 56(2):333-337. (Also in unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070519-F)
00088921	Graham, W.H.; Bornak, W.E. (1972) Greenhouse Studies with C14-Ethylene Thiourea on Potatoes and Tomatoes and Photodecomposition in Water: Laboratory 23 Research Report No. 23-52. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-G)
00097051	E.I. du Pont de Nemours & Company, Incorporated (1950) Testimony of G. Dragt: Analytical Methods. (Compilation; unpublished study received May 24, 1960 under unknown admin. no.; CDL: 130674-A)
00097064	Union Carbide Corporation (1975) Acute Toxicity of Amersperse 280 to Oyster (Crassostrea virginica) Larvae. (Unpublished study received Dec 11, 1975 under 1757-48; submitted by Drew Chemical Corp., Boonton, N.J.; CDL:224506-B)
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00107905	Conzelmann, P. (1982) Static 96-hour Marine Bioassay Testing Vinings Antimicrobial Agent AMA-31 on Grass Shrimp: GSRI Project No. 415-A60-41. (Unpublished study received Apr 22, 1982 under 9386-7; prepared by Gulf South Research Institute, submitted by Vinings Chemical Co., Atlanta, GA; CDL:247417-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Nabam Standard

MRID	CITATION
00107906	Conzelmann, P. (1982) Static 96-hour Marine Bioassay Testing Vinings Antimicrobial Agent AMA-31 on Sheepshead Minnow: GSRI Project No. 415-A60-41. (Unpublished study received Apr 22, 1982 under 9386-7; prepared by Gulf South Research Institute, submitted by Vinings Chemical Co., Atlanta, GA; CDL:247417-B)
00121050	Smith, R.; Finnegan, J.; Larson, P.; et al. (1953) Toxicologic studies on zinc and disodium ethylene bisdithiocarbamates. Journal of Pharmacology and Experimental Therapeutics 109(2): 159-166. (Also in unpublished submission received Apr 29, 1963 under 7779-3; submitted by E.F. Houghton & Co., Valley Forge, PA; CDL:008090-J)
00151954	Sernau, R. (1985) Unscheduled DNA Synthesis Rat Hepatocyte Assay with Nabam: Final Report: Project No. 752-110. Unpublished study prepared by Hazleton Biotechnologies Corp. 15 p.
00151955	Tu, A. (1985) Evaluation of Nabam in the C3H-10T 1/2 Cell System for Transformation and Promotion Activities: Final Report: Study # 54189. Unpublished study prepared by Arthur D. Little, Inc. 28 p.
00152699	Ivett, J. (1985) Clastogenic Evaluation of Nabam, 30% Water Solution in the Rat Bone Marrow Cytogenic Assay: Final Report: Project No. 22202. Unpublished study prepared by Litton Bionetics, Inc. 25 p.
00152700	Ivett, J. (1985) Clastogenic Evaluation of Nabam, 30% Water Solution in an in vitro Cytogenetic Assay Measuring Sister Chromatid Exchange in Chinese Hamster Ovary (CHO) Cells: Amended Final Report: Project No. 20990. Unpublished study prepared by Litton Bionetics, Inc. 36 p.
00152701	Cavagnaro, J.; Donoghue, E. (1985) Salmonella typhimurium/Mammalian Microsome Plate Incorporation Assay with Compound Nabam: Final Report: Project No. 752-108. Unpublished study prepared by Hazleton Biotechnologies Corporation. 21 p.
00152702	Cavagnaro, J. (1985) Host Mediated Assay in Mice with Compound Nabam: Final Report: Project No. 752-109. Unpublished study prepared by Hazleton Labs., America, Inc. 31 p.
00153559	Cavagnaro, J. (1985) CHO/HGPRT Forward Mutation Assay: Nabam: Final Report: Project No. 752-111. Unpublished study prepared by Hazleton Biotechnologies Corp. 23 p.

OFFICE OF PESTICIDE PROGRAMS
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Citations Considered to be Part of the Data Base Supporting
Registrations Under the Nabam Standard

MRID	CITATION
00156613	Puhl, R. (1986) Dermal Absorption of [Carbon-14] - Nabam in Male Rats: Final Report: Study No. 6185-100. Unpublished study prepared by Hazleton Laboratories America, Inc. 64 p.
00159693	Healy, M. (1986) Residues of Maneb and Its Metabolite E.T.U. Found in Potatoes from a Field Experiment Conducted in Piscataquis County, Maine during the 1985 Growing Season: Report #MTF-85-16. Unpublished compilation prepared by Healy and Associates in cooperation with Bio/dynamics Inc. 28 p.
00160125	Puhl, R. (1986) The Metabolism of Nabam in Rats: Final Report: Study No. 6185-101. Unpublished study prepared by Hazleton Laboratories America, Inc. 95 p.
40065801	Bontoyan, W.; Looker, J.; Kaiser, T. et al (1972) Survey of Ethylenethiorea in Commercial Ethylenebisdithiocarbamate Formulations. Journal of the AOAC. 55(5): 923-925.
40065802	Onley, J. (1977) Gas-Liquid Chromatographic Method for Determining Ethylenethiourea in Potatoes, Spinach, Applesauce, and Milk: Collaborative Study. Journal of the AOAC. 60(5): 1111-1115.
40065803	Onley, J.; Giuffrida, L.; Ives, F. et al (1977) Gas-Liquid Chromatography and Liquid Chromatography of Ethylenethiourea in Fresh Vegetable Crops, Fruits, Milk, and Cooked Foods. Journal of AOAC. 60(5): 1105-1110.
40118601	Nash, R. (1974) Pesticide Residues: Improved Gas-Liquid Chromatographic Method for Determining Ethylenethiourea in Plants. Journal of the AOAC (57:5) 1015-1021.
40118602	Kutz, F. (1979) Memorandum to Nancy Beach, EPA Office of Special Pesticide Review, dated March 12, 1979: EBDC/ETU Monitoring Study: Residue Levels of Ethylenebisdithiocarbamate and Ethylenethiourea in Sugar Beet Pulp, Molasses, Crystalline Sugar, Animal Feed Components, and Cow's Milk. 12 p.

V. FORMS APPENDICES

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data.

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

"GENERIC" DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient ______________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________ and their registration number(s) is/are ______________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: ________________ ______________________________
(Typed)

EPA Form 8570-27